Question: You're recommending restoration of the text below

> ~~In any proceeding under section 552(a) of title 5, United States Code, to obtain information the disclosure of which has been denied because of the provisions of this subsection, the Administrator may not rely on section 552(b)(3) of such title to sustain the Administrator's action.~~

But 14(a) says that EPA can't disclose anything that is exempt from disclosure under 552(a) of title 5 under exemption (b)(4).

If EPA can't release something that is FOIA-exempt under section 14, how would there be an instance in which EPA released something that would subsequently be withheld under FOIA? I'm just reading this as circular and am going to need to be able to explain it to others if I am going to be able to undo the deletion.

Response: Your email quotes text from current TSCA 14(a) referencing 552(b)(3) that does not appear in the Senate bill or offer, or any other version of the Senate bill that we have seen. Since your email asks for our thoughts on text that is apparently proposed to be stricken from the bill, we will assume that your intent was to reference section 552(b)(4), which is referenced in the Senate bill and offer. (Current TSCA section 14 contains references to both 552(b)(3) and 552(b)(4), but, again, no version of the Senate bill we have seen references (b)(3).)

As you say, section 14(a) establishes the basic standard: EPA cannot disclose information that is exempt from disclosure under subsection (a) of section 552 of Title 5, under subsection (b)(4) of that section. Subsection (c) (in the Senate Offer) provides that the information identified in that subsection (e.g., health and safety studies) "shall not be protected from disclosure", "notwithstanding subsections (a) and (b)". We think the stricken text clarifies that section 552 cannot be used as a basis for withholding from a FOIA requestor information that is made public under section 14(c). That is to say, we think it clarifies that the requirement to disclose applies notwithstanding section 552, as well as notwithstanding subsections (a) and (b) of section 14.

That having been said, the stricken text is less important under the Senate Offer and bill than it is in current TSCA. The health and safety provision of TSCA provides only that "section 14(a) does not prohibit the disclosure of" health and safety studies, leaving a more open question as to whether some other provision of law might prohibit disclosure, whereas the Senate Offer and bill more affirmatively provide that health and safety studies and other non-protected information "shall not be protected

from disclosure". So, retention of the text is arguably not critical. That having been said, we have some concern that the striking of text from current TSCA clarifying this point might be construed as signaling that the broader scope of confidentiality in FOIA Exemption (b)(4) has some residual independent impact.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 11/17/2016 1:29:58 PM
To: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
Subject: Notification: EPA Announces Public Meeting on TSCA New Chemicals Review - December 14

Jonathan,
Heads up that EPA is holding a meeting to update the public on changes to the TSCA New Chemicals Review Program on Weds, Dec 14. EPA will describe the review process for new chemicals under the amended statute, as well as discuss issues, challenges, and opportunities that the agency has identified in the first few months of implementation. Interested parties will have the opportunity to provide input on their experiences with the New Chemicals Review Program, including submittal of pre-manufacture notices (PMNs), microbial commercial activities notices (MCANs), and significant new use notices (SNUNs), under section 5 of the law. Information obtained during this meeting and from submitted written comments will be considered as EPA implements the new requirements and increases efficiency in its review process under TSCA.

Register for the meeting in advance: We ask that you please register for this meeting by December 13, 2016.

Date and Time: Wednesday, December 14, 2016, from 9:00 a.m. to 12:00 p.m.

Location: The Ronald Reagan Building and International Trade Center, Polaris Room, 1300 Pennsylvania Avenue Northwest, Washington, DC 20004

Docket number to submit written comments: EPA-HQ-OPPT-2016-0658 (Docket will be open prior to and remain open after the meeting.)

We're working on your TSCA new chemicals request and I expect to have something for you shortly. Please let me know if you would like a briefing on new chemicals program prior to or in connection with the public meeting. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/20/2016 2:02:46 AM
To: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
Subject: Re: Sen. Udall TSCA TA on Mixed confidential section

Jonathan,
Thanks for the additional info. I'll check with folks and confirm whether 10am works. Best,
Sven

On Apr 19, 2016, at 10:00 PM, Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov> wrote:

Ha ha.

How about 10am?

A reason for our asking:

Concern with restoring original senate language is it says "information that is eligible for protection under this section, that is NOT information described in paragraphs (1) and (2)" – that could be read to mean that none of process or mixture information can be protected because it is described in one of those paragraph. This needs to be much clearer that we just want information that epa can protect redacted in other documents without forcing chem id to be protected in every health and safety study.

Do we even need this provision?

Sent from my BlackBerry 10 smartphone on the Verizon Wireless 4G LTE network.

From: Kaiser, Sven-Erik
Sent: Tuesday, April 19, 2016 9:43 PM
To: Black, Jonathan (Tom Udall)
Subject: Re: Sen. Udall TSCA TA on Mixed confidential section

Jonathan,
Is this when I say that is your third wish? I'll pass along the call request - are you thinking 9:00am or so?
Thanks,
Sven

On Apr 19, 2016, at 9:42 PM, Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov> wrote:

And perhaps a call on this tomorrow morning.

Sent from my BlackBerry 10 smartphone on the Verizon Wireless 4G LTE network.

From: Black, Jonathan (Tom Udall)
Sent: Tuesday, April 19, 2016 9:39 PM
To: Kaiser, Sven-Erik
Subject: Re: Sen. Udall TSCA TA on Mixed confidential section

Also: what would be lost, if anything, by deleting this paragraph?

Sent from my BlackBerry 10 smartphone on the Verizon Wireless 4G LTE network.

From: Kaiser, Sven-Erik
Sent: Tuesday, April 19, 2016 9:35 PM
To: Black, Jonathan (Tom Udall)
Subject: Sen. Udall TSCA TA on Mixed confidential section

Jonathan,
Got it - checking. Thanks,
Sven

On Apr 19, 2016, at 9:30 PM, Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov> wrote:

Can we get epa TA drafting assistance on HLC's section 14,

14(b)(1) the mixed confidential section?

we'd like to see how you would do it?

Sent from my BlackBerry 10 smartphone on the Verizon Wireless 4G LTE network.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/24/2016 5:52:13 PM
To: 'McCarthy, David' [David.McCarthy@mail.house.gov]; Cohen, Jacqueline [jackie.cohen@mail.house.gov]
Subject: RE: Fees Langauge and TA

Dave,
Beyond the narrative TA below, we are not sure what legislative language in addition to the House proposal text you are looking at. We are concerned that any legislative TA EPA provided on fees may have passed through several parties and could be changed, so we need to see what you are looking at before we can comment. Thanks for the extra consideration. Best,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: McCarthy, David [mailto:David.McCarthy@mail.house.gov]
Sent: Thursday, March 24, 2016 1:47 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>; Cohen, Jacqueline <jackie.cohen@mail.house.gov>
Subject: Re: Fees Langauge and TA

Thanks, Sven.

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Thursday, March 24, 2016 11:42 AM
To: McCarthy, David
Subject: Re: Fees Langauge and TA

Dave,
Thanks for sending. Your email is our TA and accurately reflects our concerns with the house offer on fees. Is there specific language on fees beyond the house offer that you would like us to review. Thanks,
Sven

On Mar 24, 2016, at 11:26 AM, McCarthy, David <David.McCarthy@mail.house.gov> wrote:

From: Richards, Tina
Sent: Thursday, March 24, 2016 11:24 AM
To: kaiser.sven-eric@epa.gov <kaiser.sven-eric@epa.gov>
Cc: McCarthy, David; Kessler, Rick
Subject: Fwd: Fees Langauge and TA

Begin forwarded message:

From: "Karakitsos, Dimitri (EPW)" <Dimitri_Karakitsos@epw.senate.gov>
Date: March 11, 2016 at 11:47:53 AM EST
To: "McCarthy, David (David.McCarthy@mail.house.gov)" <David.McCarthy@mail.house.gov>, "Jerry Couri (JerryCouri@mail.house.gov)" <JerryCouri@mail.house.gov>, "Richards, Tina" <Tina.Richards@mail.house.gov>
Cc: "Jackson, Ryan (Inhofe)" <Ryan_Jackson@inhofe.senate.gov>
Subject: FW: Fees Langauge and TA

Sorry about accidentally hitting send early. Wanted to share with you all some TA our dems got on fees that raises some concerns over whether the provision Dave pointed out yesterday would do the trick for our guys.

Under either the House bill or the House offer, section 26(b)(1) provides that fees collected can be used only to "defray the cost of administering the provision of [TSCA] for which such fee is collected." In general, it will be difficult to interpret and implement restrictions on the use of fees that are expressed in terms of the particular provision of TSCA that EPA can administer using the fees, since these do not necessarily align with recognized program areas or budget categories. A more descriptive statement of the program functions for which fees can be spent would be a help to EPA in adhering to these spending restrictions.

Constraining the use of fees in this manner will likely lead to other sorts of implementation problems. For example, it appears that fees collected for data submitted under section 4 could only be used to cover the cost of collecting the information, not of using the information to perform risk evaluations. This is because the fee collection authority would be categorized under section 4, yet the use of the information in a risk evaluation would be under section 6(b). Furthermore, because CBI review obligations are undertaken under section 14, EPA could not use these fees to defray the cost of reviewing and otherwise processing CBI claims. Finally, a manufacturer's decision to request a risk evaluation may eventually result in EPA being subject to a legal obligation to undertake risk management rulemaking, but EPA could not use industry fees to defray the cost of that rulemaking.

The House offer partially addresses these implementation concerns regarding funding by adding fee collection authority for EPA initiated risk evaluations (the House bill only provides for fees to defray risk evaluation when industry requests the risk evaluation). However, the House offer still does not provide fee collection authority or other resources to defray the significant costs associated with risk management or the costs to review CBI claims. This is especially problematic in combination with the House offer's introduction of a new and very resource intensive program for the review of older CBI claims.

From: Karakitsos, Dimitri (EPW)
Sent: Friday, March 11, 2016 11:41 AM
To: McCarthy, David (David.McCarthy@mail.house.gov); Jerry Couri (JerryCouri@mail.house.gov); Richards, Tina
Cc: Jackson, Ryan (Inhofe)
Subject: Fees Langauge and TA

Dimitri J. Karakitsos
Majority Senior Counsel
Senate Committee on
Environment and Public Works
(202) 224-6176

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/5/2016 9:43:39 PM
To: 'Black, Jonathan (Tom Udall)' [Jonathan_Black@tomudall.senate.gov]; Karakitsos, Dimitri (EPW) [Dimitri_Karakitsos@epw.senate.gov]
CC: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]; Deveny, Adrian (Merkley) [Adrian_Deveny@merkley.senate.gov]
Subject: RE: SEPW TSCA TA Request on Section 14

Jonathan,
Got it – will share with the team. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Tuesday, April 05, 2016 5:42 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>; Karakitsos, Dimitri (EPW) <Dimitri_Karakitsos@epw.senate.gov>
Cc: Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov>; Deveny, Adrian (Merkley) <Adrian_Deveny@merkley.senate.gov>
Subject: RE: SEPW TSCA TA Request on Section 14

While they are at it (and lower priority than DK's request):

- The Senate has moved forward with the proposal to remove this provision:
  - ~~(D) PUBLIC INFORMATION.—No person may assert a claim under this section for protection from disclosure of information that is already publicly available.~~
  - We agree that this information would not be protected by FOIA and are ok with this decision.
  - However, we have heard concerns that eliminating this provision will be a burden on EPA to have to refute the assertion of public information over and over.
  - QUESTION: Is there a better way of taking the burden off of EPA from having to refute the assertion of public information, as opposed to penalizing the submitter? It's my impression that it is a time intensive procedure.

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Tuesday, April 05, 2016 5:36 PM
To: Karakitsos, Dimitri (EPW) <Dimitri_Karakitsos@epw.senate.gov>
Cc: Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>; Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov>; Deveny, Adrian (Merkley) <Adrian_Deveny@merkley.senate.gov>
Subject: RE: SEPW TSCA TA Request on Section 14

Dimitri – my folks are looking for it so it shouldn't be a problem. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Karakitsos, Dimitri (EPW) [mailto:Dimitri_Karakitsos@epw.senate.gov]
Sent: Tuesday, April 05, 2016 5:35 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Cc: Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>; Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov>; Deveny, Adrian (Merkley) <Adrian_Deveny@merkley.senate.gov>
Subject: RE: SEPW TSCA TA Request on Section 14

Yes I think tomorrow would be fine, hoping it shouldn't be a heavy lift since it is just really a one paragraph review and we alerted the team already.

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Tuesday, April 05, 2016 5:34 PM
To: Karakitsos, Dimitri (EPW)
Cc: Black, Jonathan (Tom Udall); Freedhoff, Michal (Markey); Deveny, Adrian (Merkley)
Subject: SEPW TSCA TA Request on Section 14

Dimitri – got it. Timing on TA – tomorrow okay? Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
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202-566-2753

From: Karakitsos, Dimitri (EPW) [mailto:Dimitri_Karakitsos@epw.senate.gov]
Sent: Tuesday, April 05, 2016 5:31 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Cc: Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>; Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov>; Deveny, Adrian (Merkley) <Adrian_Deveny@merkley.senate.gov>
Subject: Section 14

Sven,

Wanted to share with you this draft 14 change we mentioned to some of your folks on the phone today. Would appreciate TA on the move of subsection (b) into new (c) and thoughts on the particular drafting.

Thanks very much

Dimitri J. Karakitsos
Majority Senior Counsel
Senate Committee on
Environment and Public Works
(202) 224-6176

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/16/2016 1:10:09 AM
To: Michal_Freedhoff@markey.senate.gov
Subject: Sen. Markey TSCA TA request on cost considerations
Attachments: Markey TSCA TA Updated Table on Cost Considerations, 4.15.16.docx; ATT00001.htm

Michal,
The attached revised chart responds to the request for TA on cost consideration options.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

1) Can you rank these in order of added analytic burden to EPA (ie analysis above what is already required under administrative law, RIA, what EPA would expect to do as part of any rulemaking analysis, etc), and describe briefly the basis for the ranking?

2) Can you rank these in order of added litigation risk that the formulations may present, and describe (briefly) the basis for the ranking?

Cost Considerations in a Rule

- **"S 697"**

"(4) ANALYSIS FOR RULEMAKING.—

"(A) CONSIDERATIONS.—In deciding which restrictions to impose under paragraph (3) as part of developing a rule under paragraph (1), the Administrator shall take into consideration, to the extent practicable based on reasonably available information, the quantifiable and nonquantifiable costs and benefits of the proposed regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator.

"(B) ALTERNATIVES.—As part of the analysis, the Administrator shall review any 1 or more technically and economically feasible alternatives to the chemical substance that the Administrator determines are relevant to the rulemaking.

"(C) PUBLIC AVAILABILITY.—In proposing a rule under paragraph (1), the Administrator shall make publicly available any analysis conducted under this paragraph.

"(D) STATEMENT REQUIRED.—In making final a rule under paragraph (1), the Administrator shall include a statement describing how the analysis considered under subparagraph (A) was taken into account.

- **"MERGED HOUSE/SENATE PROPOSAL"**

d) PROMULGATION OF SUBSECTION (b) RULES.

(1) **REQUIREMENTS FOR RULE.—**In promulgating any rule under subsection (b) with respect to a chemical substance or mixture, the Administrator shall factor in the following considerations, and publish a statement describing how they were factored into the rule—

(A) the effects of ~~such~~ **the chemical** substance or mixture on health and the magnitude of the exposure of human beings to **the chemical** ~~such~~ substance or mixture;

(B) the effects of ~~such~~ **the chemical** substance or mixture on the environment and the magnitude of the exposure of the environment to such substance or mixture~~,~~**;**

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(C) the benefits of ~~such~~ **the chemical** substance or mixture for various uses; and ~~the availability of substitutes for such uses, and~~

(D)~~)~~ the reasonably ascertainable economic consequences of the rule, after consideration of

(i) ~~after~~ the **likely** effect ~~on~~ **of the rule on** the national economy, small business, technological innovation, the environment, and public health;~~.~~

(ii) the quantifiable and nonquantifiable costs and benefits of the proposed regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator. ;

(E) any 1 or more technically and economically feasible alternatives to the chemical substance that the Administrator determines are relevant to the rulemaking. ;

❖ **"SENATE OFFER"**

(2) REQUIREMENTS FOR RULE.—

(A) In promulgating a rule under subsection (a) with respect to a chemical substance or mixture, the Administrator shall consider and publish a statement based on reasonably available information with respect to—

(i) the effects of the chemical substance or mixture on health and the magnitude of the exposure of human beings to the chemical substance or mixture,;

(ii) the effects of the chemical substance or mixture on the environment and the magnitude of the exposure of the environment to such substance or mixture,;

(iii) the benefits of the chemical substance or mixture for various uses; and

(iv) the reasonably ascertainable economic consequences of the rule, after consideration of:

(v) the likely effect of the rule on the national economy, small business, technological innovation, the environment, and public health; and

(vi) The quantifiable and non-quantifiable costs and benefits of the proposed regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator;

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(B) In deciding which requirements to impose as part of developing the rule under subsection (a), the Administrator shall take into consideration, to the extent practicable, the considerations required under subparagraph (A).

❖ **"SUPPLEMENTED SENATE OFFER"**

(2) REQUIREMENTS FOR RULE.—

(A) In promulgating a rule under subsection (a) with respect to a chemical substance or mixture, the Administrator shall consider and publish a statement based on reasonably available information with respect to—

(i) the effects of the chemical substance or mixture on health and the magnitude of the exposure of human beings to the chemical substance or mixture,;

(ii) the effects of the chemical substance or mixture on the environment and the magnitude of the exposure of the environment to such substance or mixture,;

(iii) the benefits of the chemical substance or mixture for various uses; and

(iv) the reasonably ascertainable economic consequences of the rule, after consideration of:

(v) the likely effect of the rule on the national economy, small business, technological innovation, the environment, and public health; and

(vi) The quantifiable and non-quantifiable costs and benefits of the proposed regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator;

(B) In deciding which requirements to impose as part of developing the rule under subsection (a), the Administrator shall take into consideration, to the extent practicable, the considerations required under subparagraph (A) **and shall consider whether the proposed regulatory action and the 1 or more primary alternative regulatory actions considered by the Administrator under subparagraph (A)(vi) are cost-effective.**

❖ **"H.R. 2576 AS MODIFIED USING EPA TA"**

(B) impose requirements under the rule that the Administrator determines, to the extent practicable based on the information published under subparagraph (A), are cost-effective, except where the Administrator determines that

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additional or different requirements described in subsection (a) are necessary to ensure that the chemical substance no longer presents or will present an unreasonable risk, including an identified unreasonable risk to a potentially exposed population.

❖ **"H.R. 2576"**

(B) impose requirements under the rule that the Administrator determines, consistent with the information published under subparagraph (A), are cost-effective, except where the Administrator determines that additional or different requirements described in subsection (a) are necessary to protect against the identified risks.

❖ **SET A from EPA March 21 TA: using the term cost-effectiveness, based on Senate offer structure**

1. Add to 6(c)(2)(A)--

"(vii) the cost-effectiveness of the proposed regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator;"

2. Add the above to 6(C)(2)(A) and add the following at the end of the last sentence of 6(C)(2)(B)—

"and shall generally give preference to requirements that are more cost-effective as determined based on the consideration described in 6(c)(2)(A)(vii)"

❖ **SET B from EPA March 21 TA: not using the term cost-effectiveness, based on Senate offer structure**

1. Add to 6(c)(2)(A)—

"(vii) the efficiency with which the proposed regulatory action and the 1 or more primary alternative regulatory actions considered by the Administrator satisfy the requirement that a rule promulgated under section 6(a) ensures that the chemical substance does not present an unreasonable risk of injury to health or the environment under the conditions of use, as determined in accordance with subsection (b)(4)(A);"

2. Add the above to 6(c)(2)(A) and add the following at the end of the last sentence of 6(cC)(2)(B)—

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"and shall generally give preference to requirements that are more efficient in satisfying the requirement that a rule promulgated under section 6(a) ensures that the chemical substance does not present an unreasonable risk of injury to health or the environment under the conditions of use as determined in accordance with subsection (b)(4)(A)"

- **SET C from EPA March 21 TA: two versions of revision to House bill language, hewing closest to that language**

Version 1: (B) impose requirements under the rule that the Administrator determines, to the extent practicable based on the information published under subparagraph (A), are cost-effective, except where the Administrator determines that requirements described in subsection (a) that are in addition to or different from the cost-effective requirements the Administrator was able to identify during the rulemaking process are necessary to ensure that the chemical substance no longer presents or will present an unreasonable risk of injury to health or the environment under the intended conditions of use, including an identified unreasonable risk to a potentially exposed population.

Version 2: (B) impose requirements under the rule that the Administrator determines, to the extent practicable based on the information published under subparagraph (A), are more cost-effective than the other requirements considered by the Administrator, except where the Administrator determines that one or more of the other requirements are necessary to ensure that the chemical substance no longer presents or will present an unreasonable risk of injury to health or the environment under the intended conditions of use, including an identified unreasonable risk to a potentially exposed population.

- **SET D from EPA March 21 TA: more substantial revision to House bill language, to establish a preference rather than a presumption**

(B) generally give preference to requirements that the Administrator determines, to the extent practicable based on the information published under subparagraph (A), are more cost-effective.

- **APRIL 8 sent by Michal at 8:12 pm on April 8**

(B) impose requirements under the rule that the Administrator determines, consistent with the information published under subparagraph (A), are cost-effective, except where the Administrator determines that additional or different requirements described in subsection (a) are necessary to protect against the risk identified in a risk

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evaluation conducted under subsection (b) for the chemical substance or for a chemical substance contained in a mixture;

❖ **APRIL 15 sent by Michal at 10:22 am on April 15**

(B) in selecting requirements under subsection (a) to ensure that the [chemical] substance no longer presents or will present an unreasonable risk as determined in the risk evaluation conducted under subsection (b), choose requirements from among the one or more primary regulatory alternatives considered by the Administrator that are cost-effective based on the information published under subparagraph (A), except where the Administrator determines that none of these alternatives is sufficient to ensure that the [chemical] substance no longer presents of will present the identified unreasonable risk, in which event the Administrator shall select requirements necessary to protect fully against the risk;

❖ **APRIL 15 evening developed on conference call**

1. Add to 6(c)(2)(A)--

"(vii) the cost-effectiveness of the proposed regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator;"

Add the above to 6(C)(2)(A) and revise (B) as follows:

(B) In deciding which requirements to impose as part of developing the rule under subsection (a), the Administrator shall factor in, to the extent practicable, the considerations required under subparagraph (A).

	Burden relative to baseline	Litigation Risk

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	Burden relative to baseline	**Litigation Risk**
S. 697	**Lowest Analytical Burden Relative to Baseline** Roughly tracks E.O. 12866 requirements, but applies irrespective of whether action deemed "significant" under the E.O. Analytical burden limited to what is "practicable" and data inputs limited to what is "reasonably available" Statement describing how analysis was taken into account is already a baseline requirement of administrative law.	**Lowest Litigation Risk** Litigation opportunities to challenge rule roughly track what would already be available under APA under the substantial evidence standard, Scope of litigation would roughly track typical APA litigation, except that failure to include mandatory considerations in the overall discussion of why the rule is warranted would be a basis Most of these considerations would likely be raised by stakeholders in public comment anyway, which would establish an obligation for EPA to consider the issues, even if they were not statutorily specified.
Senate Offer	**Second Lowest Analytical Burden Relative to Baseline** The Senate Offer is identical to the Merged House/Senate proposal, except that the requirement for consideration of chemical alternatives has been deleted. This somewhat reduces analytical burden.	**Second Lowest Litigation Risk** The Senate Offer is identical to the Merged House/Senate proposal, except that the requirement for consideration of chemical alternatives has been deleted. This somewhat reduces the range of issues that might be the basis of litigation.

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	Burden relative to baseline	**Litigation Risk**
Merged House/Senate Proposal	**Third Lowest Analytical Burden Relative to Baseline** Roughly tracks E.O. 12866 requirements, but applies irrespective of whether action deemed "significant" under the E.O. Analytical burden limited to what is "practicable" and data inputs limited to what is "reasonably available" Requirement to "factor" considerations into a decisions and publish explanatory statement is already a baseline requirement of administrative law. No increase in burden from requirement to "consider and publish a statement"	**Third Lowest Litigation Risk** Litigation opportunities to challenge rule roughly track what would already be available under APA under the substantial evidence standard, Scope of litigation would roughly track typical APA litigation, except that failure to include mandatory considerations in the overall discussion of why the rule is warranted would be a basis Most of these considerations would likely be raised by stakeholders in public comment anyway, which would establish an obligation for EPA to consider the issues, even if they were not statutorily specified. Relative to H.R. 2576, list of mandatory factors is more prescriptive, somewhat increasing litigation opportunities to claim EPA failed to consider one of the points.

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	Burden relative to baseline	Litigation Risk
Supplemented Senate Offer	**Fourth Lowest Analytical Burden Relative to Baseline** The Senate Offer is identical to the Merged House/Senate proposal, except that the requirement for consideration of chemical alternatives has been deleted and a requirement to consider cost-effectiveness has been added. Overall, there is probably greater analytical burden in demonstrating that one considered cost-effectiveness than in demonstrating that one considered 1 or more chemical alternatives, so this is a slight net increase in burden.	**Fourth Lowest Litigation Risk** The Senate Offer is identical to the Merged House/Senate proposal, except that the requirement for consideration of chemical alternatives has been deleted and a requirement to consider cost-effectiveness has been added; Overall, there is probably greater litigation risk in demonstrating that one considered cost-effectiveness than in demonstrating that one considered 1 or more chemical alternatives, so this is a slight net increase in litigation risk.
April 15 evening conference call	**Fifth Lowest Analytical Burden Relative to Baseline** April 15 evening conference call version includes a requirement to consider cost effectiveness and factor it in (rather than give preference to more cost effective options).	**Fifth Lowest Litigation Risk** EPA would have to demonstrate in court that it considered the cost-effectiveness of the proposed action and of the 1 or more primary alternatives considered, and explain how it factored cost effectiveness in.
Set D	**Sixth Lowest Analytical Burden Relative to Baseline** The addition of a general preference for more cost-effective options, compared to all the preceding formulations, increases the burden, because EPA would have to develop a record to explain how it overcame the preference in rulemakings where it did so.	**Sixth Lowest Litigation Risk** EPA would have to defend in court any decision to overcome the general preference for more cost-effective options.

Commented [A1]: Ranking of this formulation is conditional, and could vary depending on the context of the bill into which it was inserted. For example, other bill provisions would determine the crucial question of how many options EPA must consider – an issue not directly addressed by this language. We have ranked them under the assumption that the required scope of analysis would be comparable to that required in Set A and B.

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	Burden relative to baseline	Litigation Risk
Set A	**Seventh Lowest Analytical Burden Relative to Baseline** Set D and A seem essentially equivalent in terms of burden. We have ranked Set A as more burdensome because Set A includes a specific requirement to consider the cost-effectiveness of the proposed action and of the 1 or more primary alternatives considered in addition to the requirement in both A and D to generally give preference to more cost-effective options. But we do not see that as a meaningful additional requirement in A, and, per the comment attached to the Set D entry, if Set D were placed in a bill that did not as clearly circumscribed EPA's analytic obligation, Set D could be considerably more burdensome than A.	**Seventh Lowest Litigation Risk** EPA would have to demonstrate in court that it considered the cost-effectiveness of the proposed action and of the 1 or more primary alternatives considered, and explain any decision to overcome the general preference for more cost-effective options.
Set B	**8th Lowest Analytical Burden Relative to Baseline** Close call between A and B, but the substitution of efficiency for cost-effectiveness probably marginally increases the burden as compared by Set A. "Efficiency" is a more general term, so EPA would have to define what it means, and then build a record to show that the standard as defined has been met.	**Eighth Lowest Litigation Risk** The substitution of efficiency for cost-effectiveness probably increases litigation risk as compared by Set A. "Efficiency" is a more general term, so EPA would have to defend its definition of the term and also defend its conclusion that the standard as defined had been met.

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	Burden relative to baseline	**Litigation Risk**
Set C Version 2	**9th Lowest Analytical Burden Relative to Baseline** The obligation to impose requirements that are more cost-effective than the other requirements considered, unless EPA determines that other requirements are necessary to ensure no unreasonable risk, imposes a higher record burden on EPA than the preference created in Sets D, A and B. This option expresses cost-effectiveness as a relative concept, in contrast to Set C Version 1, and thereby does not impose an obligation to demonstrate that the selected requirements are cost-effective in some absolute sense. That said, the formulation is best read to require EPA to select the *most* cost-effective of the options it considered, which could require substantial analysis.	**9th Lowest Litigation Risk** EPA would have to demonstrate in litigation that it selected the most cost-effective of the requirements considered, or that the selected requirements were necessary to ensure no unreasonable risk – litigation burdens not present in any of the preceding formulations.

Commented [A2]: Ranking of this formulation is conditional, and could vary depending on the context of the bill into which it was inserted. For example, other bill provisions would determine the crucial question of how many options EPA must consider – an issue not directly addressed by this language. We have ranked them under the assumption that the required scope of analysis would be comparable to that required in Set A and B.

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	Burden relative to baseline	Litigation Risk
Set C Version 1	**10th Lowest Analytical Burden Relative to Baseline** Similar to Set C Version 2, but EPA would have to define the concept of "cost-effective" used in an absolute sense and develop a record to demonstrate that the selected requirements meet the standard as so defined.	**10th Lowest Litigation Risk** Similar to Set C Version 2, but EPA would have to defend its definition of the concept of "cost-effective" used in an absolute sense. Because in EPA's view the term is typically used in a relative sense, there is some concern that the term could be interpreted to mean "cost-beneficial", which is a higher standard in EPA's view than the common understanding of cost-effectiveness. EPA would also have to defend its determination that the selected requirements meet the standard as so defined.

Commented [A3]: Ranking of this formulation is conditional, and could vary depending on the context of the bill into which it was inserted. For example, other bill provisions would determine the crucial question of how many options EPA must consider – an issue not directly addressed by this language. We have ranked them under the assumption that the required scope of analysis would be comparable to that required in Set A and B.

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	Burden relative to baseline	**Litigation Risk**
H.R. 2576 as modified by EPA TA	**11th Lowest Analytical Burden Relative to Baseline** EPA must either justify substantive economic conclusion that regulation is "cost-effective" or that a non-cost-effective alternative was "necessary." Introduces a requirement to determine that the selected option is cost-effective, or, if EPA selects a non-cost-effective option, to determine that there are no protective cost-effective options; but these analytic burdens are bounded by what is practicable based on the information already required to be considered in the rulemaking. Failure to meet the safety standard is clearly a basis to deem an alternative unacceptable. Arguably also implicitly limited by the "reasonably ascertainable" caveat in paragraph (A), regarding analysis of economic consequences.	**11th Lowest Litigation Risk** Establishes a new legal duty, above and beyond baseline obligations to justify the rule, to either make a "cost-effectiveness" determination or a "necessity" determination. The determination could be a basis for additional litigation claims. There is some uncertainty about how many cost-effective alternatives EPA must screen and find to be unsuitable in order to conclude that a non-cost-effective alternative is necessary, but this is moderated by the "practicable" language.

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	Burden relative to baseline	**Litigation Risk**
H.R. 2576	**Second Highest Introduced Burden Relative to Baseline** EPA must either justify substantive economic conclusion that regulation is "cost-effective" or that a non-cost-effective alternative was "necessary." Introduces the same analytic objectives as paragraph (B) as modified, but the analysis is less clearly bounded by the information already required to be considered in the rulemaking. Failure to meet the safety standard is very likely a basis to deem an alternative unacceptable. Arguably implicitly limited by the "reasonably ascertainable" caveat in paragraph (A), regarding analysis of economic consequences.	**Second Highest Litigation Risk** Establishes a new legal duty, above and beyond baseline obligations to justify the rule, to either make a "cost-effectiveness" determination or a "necessity" determination. The determination could be a basis for additional litigation claims. There is significant uncertainty about how many cost-effective alternatives EPA must screen and find to be unsuitable in order to conclude that a non-cost-effective alternative is necessary.

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	Burden relative to baseline	**Litigation Risk**
April 8	**Same as HR 2576—Second Highest Introduced Burden Relative to Baseline** Same comments as on HR 2576 as the only change is to delete the phrase at the end "identified risks" and replace it with "the risk identified in a risk evaluation conducted under subsection (b) for the chemical substance or for a chemical substance contained in a mixture." Do not view this change as making any significant difference in the assessment of the burdens.	**Same as HR 2576—Second Highest Litigation Risk** Same comments as on HR 2576 as the only change is to delete the phrase at the end "identified risks" and replace it with "the risk identified in a risk evaluation conducted under subsection (b) for the chemical substance or for a chemical substance contained in a mixture." Do not view this change as making any significant difference in the assessment of the litigation risk.

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	Burden relative to baseline	Litigation Risk
April 15	**Highest Introduced Burden Relative to Baseline** EPA is required to consider at least one primary regulatory alternative that is "cost-effective." This would seem to require EPA to consider possible alternatives without limit until it finds one that is cost-effective to include as a primary regulatory option, and it is not clear what happens if there are no cost-effective alternatives. Moreover, EPA may have to include an option as a primary regulatory alternative, even if it falls well short of the standard in terms of eliminating the identified risk, simply because it's benefits outweigh its costs (e.g., perhaps labeling). EPA must determine that none of the primary regulatory alternatives is sufficient to ensure that the substance presents or will present the identified risk. EPA must then determine what requirements are "necessary" to protect fully against the risk. This language seems to add yet another determination—of insufficiency of the considered primary regulatory alternatives—to the necessity determination previously included. Arguably implicitly limited by the "reasonably ascertainable" caveat in paragraph (A), regarding analysis of economic	**Highest Litigation Risk** Establishes new legal duties, above and beyond baseline obligations to justify the rule, to identify cost-effective options, to determine whether they are sufficient to ensure that the chemical no longer presents or will present the identified risks, and to determine which selected non-cost effective option is necessary. These determinations could be a basis for additional litigation claims. There is significant uncertainty about how many cost-effective alternatives EPA must screen and find to be unsuitable in order to conclude that cost effective alternatives are not sufficient to ensure that the chemical no longer presents or will present the identified risk.

	consequences.	

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/24/2016 4:49:14 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Re: Sen. Markey TSCA TA on House section 6 (4-22) - 6(i) issue

Got it - checking

On Apr 24, 2016, at 12:48 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

-we think section 7 SHOULD include the reference to 6(i) because it is supposed to be "notwithstanding" such an order, you can use the imminent hazard authority.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

From: Kaiser, Sven-Erik
Sent: Sunday, April 24, 2016 10:15 AM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA on House section 6 (4-22) - 6(i) issue

Michal,
The attached TA responds to the request on section 6(i) conforming changes raised by HLC.

Attached are our thoughts about the inclusion of reference to 6(i) orders in the sections identified. The questions largely appear to arise from the view that a section 6(i) order is something different from or more than the determination that a chemical substance does not present an unreasonable risk. As we interpret the language, Congress is merely specifying that EPA's determination is an order; it does not require EPA to issue a separate order. We believe this would be true under the APA anyway, which defines "order" as "a final disposition, whether affirmative, negative, injunctive, or declaratory in form, of any agency in a matter other than a rule making. . . ." (sec 551(6)).

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>
Date: April 23, 2016 at 9:22:05 PM EDT

To: "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov>
Subject: Re: Sen. Markey TSCA TA on House section 6 (4-22)
In conforming changes at back there are a number of places where hlc wants to know if we shd add 6(i) orders to a list of orders now covered by various sections. In some places we think yes and in others no. If you guys have a view let me know. Thx.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/3/2016 1:47:21 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
CC: Karakitsos, Dimitri (EPW) [Dimitri_Karakitsos@epw.senate.gov]; Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]; Deveny, Adrian (Merkley) [Adrian_Deveny@merkley.senate.gov]
Subject: Sen. Markey TSCA TA Request on revised section 5
Attachments: Markey.TSCA TA.section 5.docx

Michal – The attached TA responds to the request to review the revised section 5. Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Thursday, March 31, 2016 8:18 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Cc: Karakitsos, Dimitri (EPW) <Dimitri_Karakitsos@epw.senate.gov>; Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>; Deveny, Adrian (Merkley) <Adrian_Deveny@merkley.senate.gov>
Subject: Section 5 - for review

Sven

Attached is new section 5 drafted to existing TSCA. You'll see a number of specific questions we have for you in comments. We have tried to identify all the potential for drafting challenges and deviations from Senate 5 policy – but we are sure you'll find some we missed. Please give this a very careful review for anything you think we may have overlooked, drafted oddly or wrong, etc. There is no intent to meaningfully alter policy here – we are simply shifting into a re-draft using base TSCA in response to a House request that we attempt to do so. Fast turn-around appreciated.

Thanks
Michal

SEC. 5. MANUFACTURING AND PROCESSING NOTICES.

Internal x-refs where existing TSCA lettering/numbering changed have not been conformed pending review of text

(a) IN GENERAL.—(1) Except as provided in subsection (h), no person may—

(A) manufacture a new chemical substance on or after the 30th day after the date on which the Administrator first publishes the list required by section 8(b), or

(B) manufacture or process any chemical substance for a use which the Administrator has determined, in accordance with paragraph (2), is a significant new use,

unless—

(i) such person submits to the Administrator, at least 90 days before such manufacture or processing, a notice, in accordance with subsection (d), of such person's intention to manufacture or process such substance and such person complies with any applicable requirement of subsections (b), (e) or (f), and

(ii) the Administrator conducts a review of the notice, makes a determination under paragraph (3)(A), and takes any applicable action required under subsections (e) or (f).

(2) A determination by the Administrator that a use of a chemical substance is a significant new use with respect to which notification is required under paragraph (1) shall be made by a rule promulgated after a consideration of all relevant factors, including—

(A) the projected volume of manufacturing and processing of a chemical substance,

Commented [A1]: EPA TA: The addition of (e) and (f) doesn't make sense here. Subsection (a) is about requirements that apply to a prospective manufacturer prior to the commencement of manufacture (i.e., while the chemical substance is a new chemical substance). Subsection (e) and (f) relate to restrictions on the manufacturer after manufacture has commenced and the chemical substance has become an existing chemical substance.

Subsections (e) and (f) should drafted to clearly bind the manufacturer by their own terms. They shouldn't depend on (a) for their force, because (a) will cease to have any affect once manufacture legally commences.

Even if (e) and (f) belonged here, the drafting would need to read: "any applicable requirement imposed by the Administrator under (e) or (f)." Sections (e) and (f) describe how requirements on manufacturers and processors are established; they aren't themselves requirements on manufacturers or processors.

Commented [A2]: EPA TA: As currently drafted, there is a complete ban on all manufacture pending the development of information (since a 3(B) determination is not a determination under paragraph (3)(A). We presume that's not really your intention, in light of the drafting of 3(B) and 5(e), which is contradictory. Note also that 5(e) requires no action on the part of the Administrator whatsoever: it is wholly discretionary authority to impose requirements on the manufacture pending development of information.

Intuiting from the overall structure of your draft, it seems you mean to say: "the Administrator conducts a review of the notice and either: (I) makes a determination under paragraph (3)(A) and takes any applicable action required under subsection (f), or (II) makes a determination under paragraph (3)(B) and [issues an order under (e) to regulate such manufacturing or processing]."

We're not entirely sure what your intentions are with respect to that bracketed language.

(B) the extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance,

(C) the extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance, and

(D) the reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

(3) Before the end of the applicable period for review under paragraph (1), and subject to section 18, the Administrator shall review a notice received under paragraph (1) and—

(A) determine whether the relevant chemical substance or significant new use may present an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible population identified as relevant by the Administrator, [under the conditions of use identified in the notice], and take applicable action under subsection (f); or

(B) determine that additional information is necessary to make the determination under subparagraph (A), and take applicable action under subsection (b)(3).

(4) FAILURE TO ACT.—If the Administrator fails to complete its review of a notice received under paragraph (1) and make the determination required under paragraph (3) before the end of the applicable period for review under paragraph (1), including an extension pursuant to subsection (c), for reasons that cannot be attributed in whole or in part to actions or inactions of the submitter of the notice, the

Commented [A3]: EPA TA: This makes no sense. Section 18 is only about the preemption of state authority by federal authority. EPA wields federal authority, not state authority.

Commented [A4]: Question for EPA: In the past, you've told us that we should delete the "identified in the notice" language because EPA often is able to use information about similar existing chemicals to identify reasonably foreseeable conditions of use for new chemicals. We have bracketed the language here because we wonder whether EPA would typically reject or differently review a PMN for a manufacturer who is saying they are going to use the chemical for use X because EPA believes OTHER manufacturers might one day want to use the chemical for use Y? We wonder whether identified in the notice should stay here, but stay out in the SNUR part?

Commented [A5R4]: EPA TA: Yes, EPA might review a PMN bearing in mind risks from uses that the manufacturer says they don't intend. If those unintended uses may present an unreasonable risk, it would be appropriate to require (via a 5(e) order) that the manufacturer take steps to ensure that use doesn't expand into those troublesome areas as soon as the chemical hits the market. The trouble with leaving this issue to be dealt with via SNURs is that any downstream use that has already started by the time of proposal is an "ongoing" use and it is immune to being SNUR'd. So you would be leaving a gap in coverage by your suggested approach, between commencement of manufacture and proposal of the SNUR.

Commented [A6R4]: David's scenario is different from the way we implement current TSCA. If we are ok with the use(s) proposed by the PMN submitter, we do not issue a 5(e) order. We do a non-5(e) SNUR, which we are now issuing in quarterly batches (so about 90 days later). It's true that we risk a use becoming ongoing during that 90 day period, but I don't think that we have ever received comment on one of these SNURs that a use is ongoing. The non-5(e) SNURs are direct final, I believe. It's essentially a policy call that we don't believe it's necessary & appropriate to place restrictions on a PMN submitter who does not plan to pursue the use of concern. We do communicate to them that we are concerned about the other uses and will be issuing a SNUR, so they are on notice.

So, if we want to continue the current practice, I don't think including "identified in the notice" would be a problem.

Commented [A7]: EPA TA: Note that as drafted, a determination under (3)(B) doesn't lift the general bar on manufacturing under (1). Manufacture cannot commence pending the development of this additional information. We presume you didn't intend (1) to operate that way, in light of this language, and subsequent language.

Commented [A8]: We'd like your careful review of this to ensure that we capture only the appropriate circumstances in which this should occur

Commented [A9]: EPA TA: This redundant language is confusing. It suggests that if EPA merely failed to make a determination, but EPA *did* complete a review of the notice, then that would be sufficient action to avoid triggering the "failure to act" provisions. Isn't the determinative issue whether or not EPA makes a determination under paragraph (3)?

Commented [A10]: I can foresee many arguments about whether a submitter provided requested info in a timely way, etc. Not a fatal flaw if we meet our deadlines.

Administrator shall refund to the submitter of the notice any applicable fee charged to the submitter for review of the notice pursuant to section 26(b)(1). [Nothing in this paragraph shall be construed as relieving the Administrator or the submitter of the notice from any requirement of this title.]

Commented [A11]: Is there any reason to think that this would not be the case absent this sentence?

Commented [A12R11]: EPA TA: Perhaps one might argue that since 90 days have lapsed without a decision, through no fault of the submitter, EPA has made a constructive determination under (3)(A) in their favor. This is really a separate question from whether a fees refund is owed, and it seems like a fairly weak argument given that the overall thrust of the change to section 5 is to modify the status quo of TSCA where EPA silence=permission to proceed. If anything, the fees refund language tends to weaken any such constructive determination argument, since it reinforces that EPA hasn't done its job. If EPA had really made a constructive determination, there would be no reason to refund the fee.

(5) ARTICLE CONSIDERATION.—The Administrator may require notification under this section for the import or processing of a chemical substance as part of an article or category of articles under paragraph (1)(B) if the Administrator makes an affirmative finding in a rule under paragraph (2) that the reasonable potential for exposure to the chemical substance through the article or category of articles subject to the rule warrants notification.

Commented [A13]: I believe this reflects previous TA? If so, I think it's fine .

(b) SUBMISSION OF INFORMATION.—

(1)(A) If (i) a person is required by subsection (a)(1) to submit a notice to the Administrator before beginning the manufacture or processing of a chemical substance, and (ii) such person is required to submit information for such substance pursuant to a rule, order or consent agreement under section 4 before the submission of such notice, such person shall submit to the Administrator such information in accordance with such rule, order, or consent agreement at the time notice is submitted in accordance with subsection (a)(1).

(B) If—

(i) a person is required by subsection (a)(1) to submit a notice to the Administrator, and

(ii) such person has been granted an exemption under section 4(c) from the requirements of a rule or order under section 4 before the submission of such notice,

such person may not, before the expiration of the 90-day period which begins on the required date of submission of the information the submission or development of which was the basis for the exemption, manufacture such substance if such person is subject to subsection (a)(1)(A) or manufacture or process such substance for a significant new use if the person is subject to subsection (a)(1)(B).

(2)(A) If a person—

(i) is required by subsection (a)(1) to submit a notice to the Administrator before beginning the manufacture or processing of a chemical substance listed under paragraph (5), and

(ii) is not required by a rule, order, or consent agreement under section 4 before the submission of such notice to submit information for such substance,

such person shall submit to the Administrator information prescribed by subparagraph (B) at the time notice is submitted in accordance with subsection (a)(1).

(B) Information submitted pursuant to subparagraph (A) shall be information which the person submitting the information believes show that—

(i) in the case of a substance with respect to which notice is required under subsection (a)(1)(A), the manufacture, processing, distribution in commerce, use, and disposal of the chemical substance or any combination of such activities will not present an unreasonable risk of injury to health or the environment, or

Commented [A14]: We believe we do not need to qualify this use of unreasonable risk in either clause here because it does not relate to an EPA determination or action of any sort. Correct us if we are wrong.

Commented [A15R14]: EPA TA: It seems fine to leave this unqualified; it's a duty for the submitter to provide what *they think* establishes that there is not an unreasonable risk. It is even less of a problem because the UR determination that led to the placement of the chemical on the § 5(b)(4) list in the first place is qualified.

(ii) in the case of a chemical substance with respect to which notice is required under subsection (a)(1)(B), the intended significant new use of the chemical substance will not present an unreasonable risk of injury to health or the environment.

(3) If the Administrator determines under subsection (a)(3)(B) that additional information is necessary to make the determination under subsection (a)(3)(A), the Administrator—

(A) shall provide an opportunity for the submitter of the notice to submit the additional information;

(B) may, by agreement with the submitter, extend the review period for a reasonable time to allow the development and submission of the additional information;

(C) may promulgate a rule, enter into a consent agreement, or issue an order under section 4 to require the development of the information;

(D) on receipt of information the Administrator finds supports the determination under subsection (a)(3)(A), shall promptly make the determination; and

(E) may take the actions specified in subsection (e).

(4) Information submitted under paragraph (1), (2) or (3) shall be made available, subject to section 14, for examination by interested persons.

(5)(A)(i) The Administrator may, by rule, compile and keep current a list of chemical substances with respect to which the Administrator determines in accordance with subsection (a)(3)(A) that the manufacture, processing, distribution in commerce, use, or disposal, or any combination of such activities, presents or may present an unreasonable risk of injury to health or the environment.

Commented [A16]: I'm confused about the timing of what follows an insufficient info determination. We have to make the determination before the end of the review period. But it's not clear to me if there is any deadline for a rule, consent agreement or order under sect 4. Don't know if we want to raise this, but it looks like we could take a long time to follow up to require the info and in the meantime the submitter is prevented from commencing manufacture?

Commented [A17]: EPA TA: What happens if EPA makes a (3)(B) determination, and decides not to issue any 5(e) order at all?

Is that a de facto ban on the commencement of manufacture pending development of the information?

Or is that a de facto authorization to let manufacture commence, add the chemical to the rolls of existing chemical substances?

(ii) In making a finding under clause (i) that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or any combination of such activities presents or may present an unreasonable risk of injury to health or the environment, the Administrator shall consider—

(I) the effects of the chemical substance on health and the magnitude of human exposure to such substance; and

(II) the effects of the chemical substance on the environment and the magnitude of environmental exposure to such substance.

(B) The Administrator shall, in prescribing a rule under subparagraph (A) which lists any chemical substance, identify those uses, if any, which the Administrator determines, by rule under subsection (a)(2), would constitute a significant new use of such substance.

(C) Any rule under subparagraph (A), and any substantive amendment or repeal of such a rule, shall be promulgated pursuant to the procedures specified in section 553 of title 5, United States Code.

(c) EXTENSION OF NOTICE AND REVIEW PERIOD.—The Administrator may for good cause extend for additional periods (not to exceed in the aggregate 90 days) the period, prescribed by subsection (a) or (b) before which the manufacturing or processing of a chemical substance subject to such subsection may, subject to any applicable requirements under subsection (e) [or (f)] begin. Subject to section 14, such an extension and the reasons therefor shall be published in the Federal Register and shall constitute a final agency action subject to judicial review.

Commented [A18]: Senate staff don't agree on whether (f) is needed. Some of us believe that since (f) is what happens AFTER the review period ends or a determination is made it makes no sense to reference here. Others think there could be a scenario where a determination is made during an extension and we need to say it is ok for manufacture to commence if the restrictions under (f) are implemented. Request EPA TA on this point.

Commented [A19R18]: EPA TA: (f) is what happens after the review period ends and it doesn't belong here.

If there is a concern about manufacturers being forced to wait out the remainder of the review period when they already have a (3)(A) determination in hand from EPA prior to the expiration of the review period, that concern should be addressed by adding an (a)(6), to clarify that you needn't wait out your review period under those scenarios. It would be pointless since the only objective of the review period is to give EPA time to act, and EPA has already acted.

(d) CONTENT OF NOTICE; PUBLICATIONS IN THE FEDERAL REGISTER.—

(1) The notice required by subsection (a) shall include—

(A) insofar as known to the person submitting the notice or insofar as reasonably ascertainable, the information described in subparagraphs (A), (B), (C), (D), (F), and (G) of section 8(a)(2), and

(B) in such form and manner as the Administrator may prescribe, any information in the possession or control of the person giving such notice which are related to the effect of any manufacture, processing, distribution in commerce, use, or disposal of such substance or any article containing such substance, or of any combination of such activities, on health or the environment, and

(C) a description of any other information concerning the environmental and health effects of such substance, insofar as known to the person making the notice or insofar as reasonably ascertainable.

Such a notice shall be made available, subject to section 14, for examination by interested persons.

(2) Subject to section 14, not later than five days (excluding Saturdays, Sundays and legal holidays) after the date of the receipt of a notice under subsection (a) or of information under subsection (b), the Administrator shall publish in the Federal Register a notice which—

(A) identifies the chemical substance for which notice or information has been received;

(B) lists the conditions of use of such substance; and

Commented [A20]: Keeping "intended" makes sense to me. It's a new chemical or use, so at this point it is only "intended". "proposed" might be another option. Not a big problem.

(C) in the case of the receipt of information under subsection (b), describes the nature of the tests performed on such substance and any informationwhich was developed pursuant to subsection (b) or a rule, order, or consent agreement under section 4.

A notice under this paragraph respecting a chemical substance shall identify the chemical substance by generic class unless the Administrator determines that more specific identification is required in the public interest.

(3) At the beginning of each month the Administrator shall publish a list in the Federal Register of (A) each chemical substance for which notice has been received under subsection (a) and for which the period prescribed by subsection (a), (b), or (c) has not expired, and (B) each chemical substance for which such period has expired since the last publication in the Federal Register of such list.

(e) REGULATION WHEN AVAILABLE INFORMATION IS INSUFFICIENT.—(1)(A) If the Administrator determines that the information available to the Administrator is insufficient to permit the Administrator to make a determination in accordance with subsection (a)(3)(A) for a chemical substance or significant new use with respect to which notice is required by subsection (a), the Administrator may issue an order in accordance with subsection (f)(2), to take effect on the expiration of the notification and review period applicable to the manufacturing or processing of such substance under subsection (a), (b), or (c), to prohibit or otherwise restrict the manufacture, processing, distribution in commerce, use, or disposal of such substance, or manufacture or processing of the chemical substance for a significant new use, or to prohibit or otherwise restrict any combination of such activities.

(B) No person may commence manufacture of the chemical substance, or manufacture or processing of the chemical substance for a significant new use pursuant to this paragraph except in compliance with the restrictions specified in the order issued under subparagraph (A).

Commented [A21]: EPA TA: Note that 5(e) and 5(f) are now cross-referenced in an extraordinarily confusing fashion. Parts of the law governing 5(e) are now buried in 5(f), and parts of the law governing 5(f) are now buried in 5(e).

Commented [A22]: Questions for EPA. Note that we have not inserted a standard for the nature of the restrictions that need to be put into place. We have considered some options for how to do that, which include things like
"activities sufficient for the Administrator to ensure that the chemical substance or significant new use is not likely to present such a risk"
"activities sufficient for the Administrator to ensure that the chemical substance or significant new use is not likely to present an unreasonable risk"
"activities until the Administrator makes the determination in subsection (a)(3)(A)"
Our problem is that there is no "risk" defined here because the entire point is "we don't know yet, but we are pretty sure if you don't put it in the water you'll be fine making this until the test data comes back". We don't know how to define the standard of protection, and we also note that "may" and "not likely" are also not mutually exclusive. Appreciate your input here.

Commented [A23R22]: EPA TA: 5(e) regulation should be workable with exactly the same objective as 5(f) regulation ("not likely to present an unreasonable risk"). As you note below, "may present an unreasonable risk" and "not likely to present an unreasonable risk" are not mutually exclusive concepts. For exactly that reason, determining that the risk has exceeded some cutoff (e.g., "may present an unreasonable risk") is not an analytical pre-requisite to imposing restrictions sufficient to allow EPA to conclude that the chemical is "not likely to present an unreasonable risk." The new chemical review process is not analogous to the existing chemical review process, where the cutoff used to determine that regulation is necessary the flip-side of the objective for subsequent risk management regulation. Section 5 is dealing with prospective regulations to address uses that haven't even commenced: the target is simply what the Administrator finds necessary to conclude that she'll probably never need to take risk management action on an existing chemical substance that she let through the door under the new chemicals program..

Commented [A24]: EPA TA: But note: it is discretionary on EPA's part whether to issue such an order in the first place. What happens if EPA issues no such order? (B) does not resolve the question because it pre-supposes the existence of the order.

(C) Not later than 90 days after issuing an order under subparagraph (A), the Administrator shall consider whether to promulgate a rule pursuant to subsection (a)(2) that identifies as a significant new use any manufacturing, processing, use, distribution in commerce, or disposal of the chemical substance that does not conform to the restrictions imposed by the order, and, as applicable, initiate such a rulemaking or publish a statement describing the reasons of the Administrator for not initiating such a rulemaking.

(B) A proposed order may not be issued under subparagraph (A) respecting a chemical substance (i) later than 45 days before the expiration of the notification period applicable to the manufacture or processing of such substance under subsection (a), (b), or (c), and (ii) unless the Administrator has, on or before the issuance of the proposed order, notified, in writing, each manufacturer or processor, as the case may be, of such substance of the determination which underlies such order.

(C) If a manufacturer or processor of a chemical substance to be subject to a proposed order issued under subparagraph (A) files with the Administrator (within the 30-day period beginning on the date such manufacturer or processor received the notice required by subparagraph (B)(ii)) objections specifying with particularity the provisions of the order deemed objectionable and stating the grounds therefor, the proposed order shall not take effect.

(2)(A)(i) Except as provided in clause (ii), if with respect to a chemical substance with respect to which notice is required by subsection (a), the Administrator makes the determination described in paragraph (1)(A) and if—

Commented [A25]: Note here that the order relates to the conditions of use in the notice, and this would key off that – need to resolve.

Commented [A26R25]: EPA TA: This paragraph isn't establishing the scope of the SNUR authority. EPA's SNUR authority is defined under 5(a)(2), and it isn't limited to uses that a PMN submitted claimed were the intended uses. This is just telling EPA to think about whether to issue a SNUR mirroring the PMN notice. Under current drafting, EPA could consider the issue and decide, no the SNUR should go beyond the PMN notice.

Commented [A27R25]: I think they are trying to require us to consider a SNUR in follow-on to a 5(e) order, which in current practice we do for every 5(e) order. Someone is worried that we might drop that practice in the future (which is possible). Currently, we say that manufacture in any way different from what's in the order is a SNU. They may be hung up on the fact that it involves uses proposed in the PMN submission? That doesn't matter because the ACTUAL uses will be constrained by the 5(e) order, so anything else would be new.

Commented [A28]: Leg counsel needs to conform rest of subsection x-refs to reflect new subparagraphs

(I) the Administrator does not issue a proposed order under paragraph (1) respecting such substance, or

(II) the Administrator issues such an order respecting such substance but such order does not take effect because objections were filed under paragraph (1)(C) with respect to it,

the Administrator, through attorneys of the Environmental Protection Agency, shall apply to the United States District Court for the District of Columbia or the United States district court for the judicial district in which the manufacturer or processor, as the case may be, of such substance is found, resides, or transacts business for an injunction to prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of such substance (or to prohibit or limit any combination of such activities).

(ii) If the Administrator issues a proposed order under paragraph (1)(A) respecting a chemical substance but such order does not take effect because objections have been filed under paragraph (1)(C) with respect to it, the Administrator is not required to apply for an injunction under clause (i) respecting such substance if the Administrator determines, on the basis of such objections, that the determinations under paragraph (1)(A) may not be made.

(B) A district court of the United States which receives an application under subparagraph (A)(i) for an injunction respecting a chemical substance shall issue such injunction if the court finds that—

(i) the information available to the Administrator is insufficient to permit a reasoned evaluation of the health and environmental effects of a chemical substance with respect to which notice is required by subsection (a); and

Commented [A29]: EPA TA: The standard for the judge to use in litigation is out of alignment with the findings EPA was itself supposed to make. They need to align, or else there will always be an incentive to litigate, in order to obtain a better This should be: "additional information is necessary to make the determination under subsection (a)(3)(A)."

(ii)(I) in the absence of sufficient information to permit the Administrator to make such an evaluation, the manufacture, processing, distribution in commerce, use, or disposal of such substance, or any combination of such activities, may present an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible population identified as relevant by the Administrator under the conditions of use, or

(II) such substance is or will be produced in substantial quantities, and such substance either enters or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure to the substance.

Commented [A30]: EPA TA: The judicial standard here is out of alignment with the actual risk management standard. Perhaps it would work to say: "the injunction is justified, so that the manufacture, processing, distribution in commerce, use, or disposal of such substance, or any combination of such activities, is not likely to present an unreasonable risk of injury to health or environment, in accordance with subsection (a)(3)(A)."

Commented [A31]: EPA TA: This is no longer one of the criteria for issuing a 5(e) order. It should be deleted to conform.

(C) Pending the completion of a proceeding for the issuance of an injunction under subparagraph (B) respecting a chemical substance, the court may, upon application of the Administrator made through attorneys of the Environmental Protection Agency, issue a temporary restraining order or a preliminary injunction to prohibit the manufacture, processing, distribution in commerce, use, or disposal of such a substance (or any combination of such activities) if the court finds that the notification period applicable under subsection (a), (b), or (c) to the manufacturing or processing of such substance may expire before such proceeding can be completed.

(D) After the submission to the Administrator of information sufficient to evaluate the health and environmental effects of a chemical substance subject to an injunction issued under subparagraph (B) and the evaluation of such information by the Administrator, the district court of

the United States which issued such injunction shall, upon petition, dissolve the injunction unless the Administrator has initiated a proceeding for the issuance of a rule under section 6(a) respecting the substance. If such a proceeding has been initiated, such court shall continue the injunction in effect until the effective date of the rule promulgated in such proceeding or, if such proceeding is terminated without the promulgation of a rule, upon the termination of the proceeding, whichever occurs first.

(f) PROTECTION AGAINST UNREASONABLE RISKS.—(1) If the Administrator determines that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or a significant new use with respect to which notice is required by subsection (a), or that any combination of such activities, may present an unreasonable risk of injury to health or environment in accordance with subsection (a)(3)(A), —

(A) the Administrator shall issue an order, to take effect on the expiration of the notification and review period applicable under subsection (a), (b), or (c) to the manufacturing or processing of such substance, or to the significant new use, to prohibit or otherwise restrict the manufacture, processing, use, distribution in commerce, or disposal (as applicable) of the chemical substance, or manufacture or processing of the chemical substance for a significant new use, sufficient for the Administrator to determine that the chemical substance or significant new use is not likely to present such risk;

(B) no person may commence manufacture of the chemical substance, or manufacture or processing of the chemical substance for a

Commented [A32]: EPA TA: Why is this parenthetical necessary?

Commented [A33]: Question for EPA: may present and not likely to present are not mutually exclusive. Should we return to existing TSCA-like words "to the extent necessary to protect against such risk"?

Commented [A34R33]: EPA TA: The existing language is clear and workable. The fact that "may present" isn't the exact opposite of "not likely to present an unreasonable risk," shouldn't prevent EPA from implementing this as a risk management standard.

significant new use pursuant to this subsection except in compliance with the restrictions specified in the order; and

(C) not later than 90 days after issuing an order under subparagraph (A), the Administrator shall consider whether to promulgate a rule pursuant to subsection (a)(2) that identifies as a significant new use any manufacturing, processing, use, distribution in commerce, or disposal of the chemical substance that does not conform to the restrictions imposed by the order, and, as applicable, initiate such a rulemaking or publish a statement describing the reasons of the Administrator for not initiating such a rulemaking.

(2) In selecting among prohibitions and other restrictions to include in an order to be issued by the Administrator under paragraph (1) of this subsection or under subsection (e)(1)(A), the Administrator shall consider costs and other non-risk factors, and such an order may include—

(A) a requirement limiting the amount of such substance which may be manufactured, processed, or distributed in commerce,

(B) a requirement described in paragraph (2), (3), (4), (5), (6), or (7) of section 6(a), or

(C) any combination of the requirements referred to in subparagraph (B).

(3) PERSISTENT AND BIOACCUMULATIVE SUBSTANCES.—For a chemical substance the Administrator determines, with respect to persistence and bioaccumulation, scores high for 1 and either high or moderate for the other, pursuant to the TSCA Work Plan Chemicals Methods Document published by the Administrator in February 2012 (or a successor scoring system), the Administrator shall, in selecting among prohibitions and other restrictions that the Administrator determines are

Commented [A35]: Is this now a non-exclusive list, since the order "may include"? Or does it mean it may not include anything else? May not be an issue if the change in David's next comment is made.

Commented [A36]: Question for EPA: do we need to add or change based on our 6(a) list in order to capture everything EPA currently can do?

Commented [A37R36]: EPA TA: Yes. 5(e) orders are now being limited to the particular restrictions available under 5(f)(2). Under current TSCA, there is no such limitation on 5(e). In order to maintain current flexibility with respect to 5(e) orders, while still providing here that 5(e) orders can only impose restrictions enumerated in 6(a)(2)-(7), a catch-all authority needs to be added to 6(a): to "otherwise restrict" the manufacture, processing, or distribution in commerce of the chemical

sufficient to address such risk identified in accordance with subsection (a)(3)(A), reduce potential exposure to the substance to the maximum extent practicable.

(4) WORKPLACE EXPOSURES.—To the extent practicable, the Administrator shall consult with the Assistant Secretary of Labor for Occupational Safety and Health prior to adopting any prohibition or other restriction under this subsection to address workplace exposures.

(3)(A) The Administrator may—

(i) issue a proposed order to prohibit the manufacture, processing, or distribution in commerce of a substance with respect to which a finding was made under paragraph (1), or

(ii) apply, through attorneys of the Environmental Protection Agency, to the United States District Court for the District of Columbia or the United States district court for the judicial district in which the manufacturer, or processor, as the case may be, of such substance, is found, resides, or transacts business for an injunction to prohibit the manufacture, processing, or distribution in commerce of such substance.

A proposed order issued under clause (i) respecting a chemical substance shall take effect on the expiration of the notification period applicable under subsection (a), (b), or (c) to the manufacture or processing of such substance.

(B) If the district court of the United States to which an application has been made under subparagraph (A)(ii) finds that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance with

Commented [A38]: Different way to address the "may" and "not likely" can both be true at once problem. Does this work?

Commented [A39R38]: EPA TA: This is a less clear approach, because the reader has to infer what it means to "address the risk." Presumably the standard is restriction sufficient so that the manufacture, processing, distribution in commerce, use, or disposal of such substance, or any combination of such activities, is not likely to present an unreasonable risk of injury to health or environment, in accordance with subsection (a)(3)(A)."

Commented [A40]: EPA TA: It would be helpful to clarify that this is to "further" reduce potential exposure.

Commented [A41]: I believe that our current practice is to ban pending upfront testing for new chems that meet the PBT criteria, the justification being that with any exposure/release there is the potential for reaching an unreasonable risk level at some point in the future. Could a ban be "practicable"? I would argue it is, with the exception of cases where the new chemical is the only alternative to something that is worse. But if we took this approach, would it be vulnerable to challenge?

Commented [A42]: I think we decided earlier that this is ok, since we can interpret it to include consulting on approaches and policies, rather than case by case. Correct?

Commented [A43]: Leg counsel to conform x-refs as needed in para (3)

Commented [A44]: EPA TA: This requires more work than just conforming x-refs by leg counsel. You currently have two different competing paragraphs describing EPA's authority to issue 5(f) orders. One is mandatory (5(f)(1) and the other is discretionary 5(f)(3)). This is an artifact of how you repurposed paragraphs 5(f)(1) and 5(f)(2), which in current TSCA describe EPA deciding whether to use a section 6 rule or a section 5 order to deal with an unreasonable risk.

Commented [A45R44]: Does this also limit our options under 5(f) to a ban?

Commented [A46]: EPA TA: This judicial standard is out of alignment with how you've revised the underlying risk management objective of 5(f). You're trying to conform the judicial review language of 5(f) from current TSCA. Under 5(f) of current TSCA, though, EPA needs to make a "presents or will present" finding. The administrative analytical standard under 5(f)(A), however, is now not likely to present an unreasonable risk. It doesn't make sense for EPA to have to prove more in litigation than it was trying to prove to itself when issuing the original administrative order.

Just as the risk management standards of 5(e) and 5(f) can be the same, the judicial standards can be the same. We think the standard you're intending is: "the injunction is justified, so that the manufacture, processing, distribution in commerce, use, or disposal of such substance, or any combination of such activities, is not likely to present an unreasonable risk of injury to health or environment, in accordance with subsection (a)(3)(A)."

respect to which such application was made, or that any combination of such activities, presents or will present an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible population identified as relevant by the Administrator under the conditions of use, before a rule promulgated under section 6 can protect against such risk, the court shall issue an injunction to prohibit the manufacture, processing or distribution in commerce of such substance or to prohibit any combination of such activities.

Commented [A47]: Question for EPA: Ok to reference our language in section 6 that we use for REs that describes all of these instead of writing it all down twice?

Commented [A48R47]: As noted above, there's a broader problem here. Why is EPA proving in court that there is an unreasonable risk, when the original 5(f) order was founded on a "may present" finding?

(C) The provisions of subparagraphs (B) and (C) of subsection (e)(1) shall apply with respect to an order issued under clause (i) of subparagraph (A); and the provisions of subparagraph (C) of subsection (e)(2) shall apply with respect to an injunction issued under subparagraph (B).

(D) If the Administrator issues an order pursuant to subparagraph (A)(i) respecting a chemical substance and objections are filed in accordance with subsection (e)(1)(C), the Administrator shall seek an injunction under subparagraph (A)(ii) respecting such substance unless the Administrator determines, on the basis of such objections, that such substance does not or will not present an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible population identified as relevant by the Administrator under the conditions of use.

Commented [A49]: EPA TA: Same issue as noted above.

(g) STATEMENT OF REASONS FOR NOT TAKING ACTION.—If the Administrator finds, in accordance with subsection (a)(3)(A), that a determination that the relevant chemical substance or significant new use

may present an unreasonable risk of injury to health or the environment is not justified, then notwithstanding any remaining portion of the period for review under subsection (a), (b), or (c) applicable to the manufacturing or processing of such substance or significant new use, the submitter of the notice may commence manufacture for commercial purposes of the chemical substance or manufacture or processing of the chemical substance for a significant new use, and the Administrator shall publish a statement of the Administrator's finding . Such a statement shall be published in the Federal Register before the expiration of such period. Publication of such statement in accordance with the preceding sentence is not a prerequisite to the manufacturing or processing of the substance with respect to which the statement is to be published.

Commented [A50]: Question for EPA: This is our solution to the "may" and "not likely" can both be true at the same time problem for this subsection. Does it work? We can't say "does not determine" because that leaves open the potential that EPA just doesn't make a determination at all. We are trying to find words that say "EPA did what it was supposed to do and did not find "may present". Any issues w the words "find' or "findng"? Especially as it relates to any judicial reviewability implications? I don't think that the "safe" finding under Senate offer 5 met Bennet v Spear standards and I am not sure this is any different, but tell us if you disagree.

Commented [A51R50]: How about "if the Administrator does not determine that the substance presents…."? This is awkward, but I don't like introducing "justified".

They need to change the title of the subsection too.

Commented [A52]: EPA would need to notify the submitter of it's decision to make this worthwhile. The statement to be published in the FR must be before the end of the period, but that could be Day 89. Probably not worth raising and imposing another deadline on ourselves. Will let industry worry about it.

(h) EXEMPTIONS.—(1) The Administrator may, upon application, exempt any person from any requirement of subsection (a) or (b) to permit such person to manufacture or process a chemical substance for test marketing purposes—

(A) upon a showing by such person satisfactory to the Administrator that the manufacture, processing, distribution in commerce, use, and disposal of such substance, and that any combination of such activities, for such purposes will not present any unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible population identified by the Administrator for the specific uses identified in the application, and

(B) under such restrictions as the Administrator considers appropriate.

Commented [A53]: Should this be conditions of use? Our thinking was the application would be for specific uses and not for the breadth of uses EPA might consider when contemplating a SNUR. Tell us if we are wrong.

Commented [A54R53]: Why not "intended conditions of use" or whatever is in 5(d)?

(2)(A) The Administrator may, upon application, exempt any person from the requirement of subsection (b)(2) to submit information for a chemical substance. If, upon receipt of an application under the preceding sentence, the Administrator determines that—

Commented [A55]: Leg counsel to conform internal X-refs here if needed

(i) the chemical substance with respect to which such application was submitted is equivalent to a chemical substance for which information has been submitted to the Administrator as required by subsection (b)(2), and

(ii) submission of information by the applicant on such substance would be duplicative of information which has been submitted to the Administrator in accordance with such subsection,

the Administrator shall exempt the applicant from the requirement to submit such informationon such substance. No exemption which is granted under this subparagraph with respect to the submission of information for a chemical substance may take effect before the beginning of the reimbursement period applicable to such information.

(B) If the Administrator exempts any person, under subparagraph (A), from submitting information required under subsection (b)(2) for a chemical substance because of the existence of previously submitted information and if such exemption is granted during the reimbursement period for such information, then (unless such person and the persons referred to in clauses (i) and (ii) agree on the amount and method of reimbursement) the Administrator shall order the person granted the exemption to provide fair and equitable reimbursement (in an amount determined under rules of the Administrator)—

(i) to the person who previously submitted the informationon which the exemption was based, for a portion of the costs incurred

by such person in complying with the requirement under subsection (b) (2) to submit such information, and

(ii) to any other person who has been required under this subparagraph to contribute with respect to such costs, for a portion of the amount such person was required to contribute.

In promulgating rules for the determination of fair and equitable reimbursement to the persons described in clauses (i) and (ii) for costs incurred with respect to a chemical substance, the Administrator shall, after consultation with the Attorney General and the Federal Trade Commission, consider all relevant factors, including the effect on the competitive position of the person required to provide reimbursement in relation to the persons to be reimbursed and the share of the market for such substance of the person required to provide reimbursement in relation to the share of such market of the persons to be reimbursed. For purposes of judicial review, an order under this subparagraph shall be considered final agency action.

(C) For purposes of this paragraph, the reimbursement period for any previously submitted information for a chemical substance is a period—

(i) beginning on the date of the termination of the prohibition, imposed under this section, on the manufacture or processing of such substance by the person who submitted such informationto the Administrator, and

(ii) ending—

(I) five years after the date referred to in clause (i), or

(II) at the expiration of a period which begins on the date referred to in clause (i) and is equal to the period which the

Administrator determines was necessary to develop such information

whichever is later.

(3) The requirements of subsections (a) and (b) do not apply with respect to the manufacturing or processing of any chemical substance which is manufactured or processed, or proposed to be manufactured or processed, only in small quantities (as defined by the Administrator by rule) solely for purposes of—

(A) scientific experimentation or analysis, or

(B) chemical research on, or analysis of such substance or another substance, including such research or analysis for the development of a product,

if all persons engaged in such experimentation, research, or analysis for a manufacturer or processor are notified (in such form and manner as the Administrator may prescribe) of any risk to health which the manufacturer, processor, or the Administrator has reason to believe may be associated with such chemical substance.

(4) The Administrator may, upon application and by rule, exempt the manufacturer of any new chemical substance from all or part of the requirements of this section if the Administrator determines that the manufacture, processing, distribution in commerce, use, or disposal of such chemical substance, or that any combination of such activities, will not present an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible population identified by the Administrator under the conditions of use.

Commented [A56]: We thought this one should be conditions of use since it is a broader exemption. Tell us if we are wrong.

Commented [A57R56]: I'm not sure what conditions of use adds to this finding. Does it modify exposed or susceptible population? Or the potential for risk?

(4) The Administrator may, upon application, make the requirements of subsections (a) and (b) inapplicable with respect to the

manufacturing or processing of any chemical substance (A) which exists temporarily as a result of a chemical reaction in the manufacturing or processing of a mixture or another chemical substance, and (B) to which there is no, and will not be, human or environmental exposure.

(5) Immediately upon receipt of an application under paragraph (1) or (4) the Administrator shall publish in the Federal Register notice of the receipt of such application. The Administrator shall give interested persons an opportunity to comment upon any such application and shall, within 45 days of its receipt, either approve or deny the application. The Administrator shall publish in the Federal Register notice of the approval or denial of such an application.

(i) DEFINITIONS.—

(1) For purposes of this section, the terms ''manufacture'' and ''process'' mean manufacturing or processing for commercial purposes.

(2) For purposes of this Act, the term 'requirement' as used in this section does not displace common law.

Commented [A58]: What does this mean?

[15 U.S.C. 2604]

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/29/2016 4:23:24 PM
To: Couri, Jerry [JerryCouri@mail.house.gov]
Subject: HEC TSCA TA request on TSCA section 5(b)(1)(B)

Jerry,
This TA responds to the request on section 5(b)(1)(B).

Section 5(b)(1)(B) provides for a later end to the review period in the scenario where:

1) Certain data are generally required to be submitted along with a PMN or SNUN (due to a previously issued test rule); and
2) A prospective manufacturer opts not to submit those test data with its PMN or SNUN, but instead requests an exemption (e.g., on the ground that some other entity is doing the testing, or the prospective manufacturer can otherwise submit data substantiating their exemption request)

In this case, then the 90 day review period is tolled until the information that is the basis for the exemption actually reaches EPA (e.g., the test rules from the other entity, or the information showing that the prospective manufacturer is otherwise entitled to a testing exemption).

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any additional questions. Thanks,

Sven

Sven-Erik Kaiser

U.S. EPA

Office of Congressional and Intergovernmental Relations

1200 Pennsylvania Ave., NW (1305A)

Washington, DC 20460

202-566-2753

On Apr 29, 2016, at 11:32 AM, Couri, Jerry <JerryCouri@mail.house.gov> wrote:

Before we come to a decision on later today, I have a simple question from the TA on the definition of 'applicable review period' on Page 29:

The TA suggested that the 'applicable review period' might end on a date "as is provided for in subsection (b)". Unless I am missing something, I don't read an explicit extension in section 5(b). How does section 5(b) create this extension?

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Friday, April 29, 2016 10:44 AM
To: Couri, Jerry
Subject: Re: HEC TSCA TA request on TSCA section 5

Jerry- I misunderstood our availability. The attorney on this is only available until 3. Any chance 2 or 2:30 works?
Apologies,
Sven

On Apr 29, 2016, at 10:30 AM, Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov> wrote:

Jerry, Okay- let's aim for 3pm - 866-299-3188, code 202-564-2910#. Just let me know if your schedule changes as we can push it back if needed. Thanks,
Sven

On Apr 29, 2016, at 10:28 AM, Couri, Jerry <JerryCouri@mail.house.gov> wrote:

OK. Thanks. Likely 3p is better.

Sent from my BlackBerry 10 smartphone on the Verizon Wireless 4G LTE network.

From: Kaiser, Sven-Erik
Sent: Friday, April 29, 2016 10:26 AM
To: Couri, Jerry
Subject: HEC TSCA TA request on TSCA section 5

Jerry - are you available for a clarifying call at 11am or after 3pm?

We think you are asking whether -- if changes are made to 5a3B so it aligns with the current trigger language for 5(e) (rather than conforming the trigger language for 5(e) to the new 5a3B -- that would obviate the need for some or all of the other suggested changes in 5e. We think the answer is no. Most or all of the other changes have to do with converting 5e from a blocking provision to an enabling provision and are not impacted by the specific trigger.
Thanks,
Sven

On Apr 29, 2016, at 9:45 AM, Couri, Jerry <JerryCouri@mail.house.gov> wrote:

Part of it relates to whether putting 5(e)(1)(A) into 5(a)(3)(B), what would be the effect of not changing 5(e) further and if change necessary, how much of the previous TA stands?

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Thursday, April 28, 2016 8:55 PM
To: Couri, Jerry
Subject: Re: TA request on TSCA section 5

Jerry,

This TA responds to the request on section 5(e).

We sent suggested changes both to the new 5(a)(3)(B) (to align with 5(e)) and to 5(e)(1)(A) (e.g., to remove the language about substantial production, release and exposure, which is not part of the 5(a)(3)(B) finding under your draft). Do you have specific questions about the changes we suggested to the lead in to 5(e)? See attachments for the most recent section 5 TA.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
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202-566-2753

On Apr 28, 2016, at 5:53 PM, Couri, Jerry <JerryCouri@mail.house.gov> wrote:

Sven:

Thanks to you and the folks at EPA for the TA on section 5. We have a follow-up question on what you sent to us:

If we change the wording in proposed new section 5(a)(3)(B) to match existing section 5(e) -- as I think the Agency's TA suggests, would we need to change the lead in to existing 5(e)?

Thanks.

- Jerry

Gerald S. Couri
Senior Environmental Policy Advisor | Committee on Energy and Commerce
U.S. House of Representatives
2125 Rayburn Building | 202.226.9603 (direct)

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/12/2016 2:33:22 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Re: Sen. Markey TSCA TA on section 5 "may present"

Michal- we can do 10:30am this morning. Please call Ex. 6 - Personal Privacy code Ex. 6 - Personal Privacy. Thanks,
Sven

On Mar 12, 2016, at 9:03 AM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Btw 10:30-1:30 prob best but I can make other options work too if needed

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

From: Kaiser, Sven-Erik
Sent: Saturday, March 12, 2016 8:24 AM
To: Freedhoff, Michal (Markey)
Subject: Re: Sen. Markey TSCA TA on section 5 "may present"

Michal, checking. Availability today for a call? Thanks,
Sven

On Mar 12, 2016, at 6:29 AM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Sven

Not sure if this is best left for a call rather than an email exchange. Your drafting suggestions make sense to me.

But I'm also interested in more of a policy discussion about what dropping the requirement that EPA explicitly make an "unlikely to present" (ie the (2)(B) finding) means.

There appear to be very strong and diverse views on this point, which include:

- it is impossible to make such a finding about a new chemical and doing so would provide people with a false sense of safety related to the chemical
- it is impossible to make such a finding about a new chemical and requiring EPA to do so would result in no new chemicals ever being allowed onto the market
- removing the requirement to make such a finding would represent an enormous concession and policy shift from current senate position because every chemical should be deemed safe before it enters the marketplace

The option we are discussing says "tell me if it is unsafe. If it is, fix the problem. If you don't know, find out and then fix the problem if there is one". To me, inherent and embedded in that is a requirement that EPA make a safety determination - safe or unsafe- even if we are not explicitly requiring epa to pronounce a new chemical to be safe. Others disagree with me completely. I'd like EPA's views.

Thanks
M

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

From: Kaiser, Sven-Erik
Sent: Friday, March 11, 2016 9:24 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA on section 5 "may present"

Michal, this responds to your YA request in section 5 determinations. Please see the attached TA along with the comments below.

Option #1 … This won't work well. If EPA has a basis to say that a chemical substance "may present" an UR, there is no direction about whether to make that finding or whether to just give the chemical a pass, which is an alternative option. The intention is presumably that EPA can make the "may commence" finding only if EPA has no basis to make the "may present" finding, but the language does not say that. This option also presents some of the issues identified for option 2.

Option 2 seems to provide clearer direction but raises some issues, identified, with suggested possible fixes, in the attachment.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/11/2016 7:33:33 PM
To: 'Black, Jonathan (Tom Udall)' [Jonathan_Black@tomudall.senate.gov]
Subject: RE: Sen. Udall TSCA TA request on Industry nominated chemicals

Jonathan,
Thanks for the clarification on the TA request. Best,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Monday, April 11, 2016 3:29 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Udall TSCA TA request on Industry nominated chemicals

You can use this version...

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Monday, April 11, 2016 2:56 PM
To: Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>
Subject: RE: Sen. Udall TSCA TA request on Industry nominated chemicals

Jonathan,
Do you have a minute for a call to clarify the request? Can call me at Ex. 6 - Personal Privacy and I'll loop in the attorney working on this one. Thanks,
Sven

Sven-Erik Kaiser
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Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Monday, April 11, 2016 1:55 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Re: Sen. Udall TSCA TA request on Industry nominated chemicals

No, it's my bad.

The new offer.

I think they should both be the same on this provision?

Sent from my BlackBerry 10 smartphone on the Verizon Wireless 4G LTE network.

From: Kaiser, Sven-Erik
Sent: Monday, April 11, 2016 1:52 PM
To: Black, Jonathan (Tom Udall)
Subject: RE: Sen. Udall TSCA TA request on Industry nominated chemicals

Jonathan – Apologies about the mix up. Can you confirm which version to work from - senate offer (3/3) or new senate offer that came in over the weekend. Thanks,
Sven

Sven-Erik Kaiser
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Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Monday, April 11, 2016 1:44 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Re: Sen. Udall TSCA TA request on Industry nominated chemicals

Thanks Sven, I should have asked for you to draft to the Senate offer.

Possible to see that? Sorry.

Sent from my BlackBerry 10 smartphone on the Verizon Wireless 4G LTE network.

From: Kaiser, Sven-Erik
Sent: Monday, April 11, 2016 1:33 PM
To: Black, Jonathan (Tom Udall)
Subject: Sen. Udall TSCA TA request on Industry nominated chemicals

Jonathan,
This TA responds to the request on industry nominated chemicals.

QUESTION: EPA has indicated that the House bill allows industry nominated chemicals to overwhelm EPA's priorities.

Is there a way to draft the house bill/proposal to allow for industry nominated chemicals to move through "without a cap" (as per the senate bill), but also without compromising EPA's priorities?

Response:
The language in question is for the House offer. It would also work with minor adjustment for the House bill as passed. There is no min/max provision in the House bill as passed, so that part has to be deleted if you are modifying the House bill as passed.

House offer

6(b)(7) MINIMUM NUMBER.--

(A) IN GENERAL.-- Subject to the availability of appropriations, the Administrator shall initiate 10 or more risk evaluations under paragraph (3)(A)(i) or (3)(B) in each fiscal year beginning in the fiscal year of the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

(B) LIMITATION.-- Notwithstanding any other provision of this section, if the Administrator does not initiate 10 or more risk evaluations under (A) in any complete fiscal year following the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, then in the following fiscal year the Administrator shall not accept any requests under paragraph (3)(A)(ii) and is not subject to paragraph (3)(C)(i)(I), unless in that fiscal year the Administrator has first initiated 10 risk evaluations under (A).

House bill as passed

6(b)(7) MINIMUM NUMBER.--

(A) IN GENERAL.-- Subject to the availability of appropriations, the Administrator shall initiate 10 or more risk evaluations under paragraph (3)(A)(i) or (3)(B) in each fiscal year beginning in the fiscal year of the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

(B) LIMITATION.-- Notwithstanding any other provision of this section, if the Administrator does not initiate 10 or more risk evaluations under (A) in any complete fiscal year following the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, then in the following fiscal year the Administrator shall not accept any requests under paragraph (3)(A)(ii) unless in that fiscal year the Administrator has first initiated 10 risk evaluations under (A).

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: "Black, Jonathan (Tom Udall)" <Jonathan_Black@tomudall.senate.gov>
Date: April 10, 2016 at 6:07:41 PM EDT
To: "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov>
Subject: Industry nominated chemicals

Hi Sven,

EPA has indicated that the House bill allows industry nominated chemicals to overwhelm EPA's priorities.

Is there a way to draft the house bill/proposal to allow for industry nominated chemicals to move through "without a cap" (as per the senate bill), but also without compromising EPA's priorities?

Sent from my BlackBerry 10 smartphone on the Verizon Wireless 4G LTE network.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/17/2016 6:33:32 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: RE: TSCA TA - Section 6 Issue

Michal - are you referring to 26(j)(4)? If so, that does not address the issue.

The provision allows EPA to continue section 6 work while the policies, procedures and guidance required under the bill are being developed. But it does not address the issue of how the "partial" risk assessments or determinations that EPA is currently pursuing would fit into the new section 6 structure.

Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Thursday, March 17, 2016 2:21 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Re: TSCA TA - Section 6 Issue

Question - what about our section 26 language

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

From: Kaiser, Sven-Erik
Sent: Thursday, March 17, 2016 2:10 PM
To: Freedhoff, Michal (Markey)
Subject: TSCA TA - Section 6 Issue

Michal,
In reviewing bill text (house and senate passed bills), EPA just discovered a technical issue that will have significant policy implications for EPA's ongoing work under Section 6. As currently drafted, both Senate and House bills could frustrate EPA's ability to timely manage risks that have been (or may be) identified in our current Work Plan risk assessments.

As you know, EPA has been working on risk assessments (draft and final) for a number of chemical substances - TCE, NMP, MC, and 1-BP. These risk assessments have been scoped relatively narrowly, so as to focus the Agency's resources on uses most likely to present risk. EPA is *not* looking at all the conditions of use for these chemicals.

This approach, which might be characterized as a *partial* risk evaluation or *partial* safety determination, we see as simply not contemplated under the Senate and House bills. The section 6 structure in both bills would require EPA to assess a chemical in its entirety, based on all conditions of use – not just a subset of those uses.

Should the House/Senate construct become law, the Agency would be left with a difficult choice in moving forward with our ongoing Work Plan assessment and rules.

One option might be to move forward with finalizing the risk evaluation and regulating a subset of chemical uses. There's some risk that the new law would not support such an interpretation. Even if it would, the risk management deadline for the chemical would start ticking immediately. That means that EPA would be on the clock to expand the risk evaluation to cover remaining non-scoped uses, finalize those determinations, AND complete a rulemaking to manage any associated risks. For risk assessments that are draft or final, this appears to be the public policy preferred option. It's highly unlikely that EPA would be able to complete this work for non-scoped uses within the statutory timeframes.

Alternatively, EPA could hold off on moving to risk management finalizing and spend additional time evaluating the full suite of uses. This would have the practical effect of allowing known risks to health or the environment (i.e., those identified in the narrowly-scoped assessment) to continue unregulated during this period.

We'd welcome an opportunity to work with you on a drafting solution to this issue, but wanted to bring to your attention as soon as possible.

Sven-Erik Kaiser
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Washington, DC 20460
202-566-2753

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 12/8/2016 6:51:41 PM
To: Couri, Jerry [JerryCouri@mail.house.gov]
Subject: HEC Inquiry on TSCA interim status and suspensions

Jerry, thanks for the question about TSCA interim status and suspensions.

When advised of the interim status of their case, submitters usually request a suspension of the review period so that they can either provide the Agency additional information to inform its decision, or work with EPA on development of a consent order. Some submitters decide to withdraw their notifications when advised of the interim status. The submitters of 18 of these notifications have withdrawn their notifications as of Dec 6, 2016.

As noted, of the 321 valid "re-set" cases that were under review by EPA, most of the 206 cases for which EPA had previously made decisions to develop orders or to seek additional information from submitters were already in suspension on June 22. New suspensions past the reset Day 90 of September 19 were requested by the submitters for most of these 206 cases and the other 115 cases that were "re-set." Suspensions were not needed for the 18 cases that were withdrawn by the submitters. Also, for the 22 cases that were determined "not likely to present an unreasonable risk," suspensions were not needed. The submitters of the remaining 281 cases have requested suspensions.

Please let me know if any additional questions. The congressional staff briefing on Mon, Dec 12 at 2pm in 406 Dirksen provides an additional opportunity to discuss your questions and the New Chemicals Review program.
Best,
Sven

Sven-Erik Kaiser
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Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Couri, Jerry [mailto:JerryCouri@mail.house.gov]
Sent: Wednesday, October 26, 2016 2:10 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: EPA Notification: TSCA New Chemicals Update

ALL the interims agreed to an suspension/extension? How many is that? Seems a bit odd....

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Wednesday, October 26, 2016 2:03 PM
Subject: EPA Notification: TSCA New Chemicals Update

Heads up that EPA updated the TSCA FAQs to add information on new chemical reviews. The new FAQ (#23) is included below, the full FAQs are available at https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act-0#newchems.

EPA will continue to update the FAQs as TSCA reform implementation progresses. Please let me know if any questions. Thanks,
Sven

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Office of Congressional and Intergovernmental Relations
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Washington, DC 20460
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Q23. What's the status of new chemical reviews now that the first 90 days has passed?

The Frank R. Lautenberg Chemical Safety for the 21st Century Act went into effect immediately upon signature by the President on June 22, 2016. The New Chemicals Program was the most immediately affected part of the EPA's TSCA program. Amended TSCA, section 5, requires the EPA to review a new chemical or new use notice, make a determination, and to take actions required in association with that determination. In implementing this new provision, EPA is working diligently to make decisions in a time frame that comes as close as possible to that experienced prior to the new law.

EPA receives new chemical submissions totaling about 1,000 per year. As a result, on June 22, several hundred chemicals were at different stages in the review process. Section 5 submissions were considered resubmitted, thus restarting the 90-day clock for EPA's review of those chemicals. The EPA then faced a number of challenges, including:

- Doubling effort on review processes to reconsider pre-enactment decisions in light of the new standard for resubmitted PMNs, while keeping pace with new submissions.
- Developing and implementing a process for implementing the "not likely to present an unreasonable risk" finding, including new documentation and publication requirements.
- Implementing the provision of the new law which requires that EPA make an affirmative determination for both intended and reasonably foreseen uses of new chemicals.
- Implementing the new finding of "insufficient information to make a reasoned evaluation."

With the 90-day clock running on several hundred submissions, it took the EPA several weeks to put these components into place, including adding staff to review new chemicals, scheduling additional reviews, developing affirmative finding documents which meet legal requirements and provide useful information on EPA's reviews.

By the end of September 2016, EPA reached interim or final determinations for most of the new chemical submissions which were resubmitted when the new law was enacted. All submitters with interim determinations have requested, and EPA has granted, a suspension of the 90-day review period.

- On June 22, 2016, there were about 200 chemicals in the process for which EPA had previously made decisions to develop orders or to seek additional information from submitters, based on a finding that each chemical "may present an unreasonable risk". The review period for these chemicals had been voluntarily suspended by the submitters. EPA determined that the decisions on these chemicals would remain the same under the new law. Submitters have agreed to re-suspend the review period while orders are being developed or negotiated.
- That left about 115 valid submissions within the 90-day review period on June 22. EPA re-reviewed these chemicals in light of the new requirements and made decisions prior to day 90.
- New chemical submissions received after June 22 are being reviewed and will receive final or interim determinations within a 90-day review period.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/24/2016 5:38:00 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]; 'Black, Jonathan (Tom Udall)' [Jonathan_Black@tomudall.senate.gov]; 'Deveny, Adrian (Merkley)' [Adrian_Deveny@merkley.senate.gov]
Subject: RE: Sen. Markey TSCA TA request on section 8 nomenclature language

Michal – additional TA responding to the request on nomenclature.

First, we do believe we have the authority under section 8(b)(2) of current TSCA to designate new statutory mixtures.

Second, while the comments we made identified concerns with (A)(iii), we also have additional concerns with (B)(i) that we hope to get to you on Monday. The (B)(i) concerns are those that we stated we needed more time to fully articulate.

Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
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1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, March 22, 2016 6:40 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>; Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>; Deveny, Adrian (Merkley) <Adrian_Deveny@merkley.senate.gov>
Subject: RE: Sen. Markey TSCA TA request on section 8 nomenclature language

Re statutory mixtures – does EPA currently have authority to designate new statutory mixtures? I think the intent of the language is to ensure that EPA could add new mixtures in the future and no intent to create the court argument you're fearing.

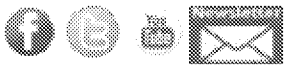
Also, are your concerns with (A)(iii) or (B)(i)? your email says the latter but your comments are on the former.

Monday shouldn't be a problem but the answer to the question on EPA authority with statutory mixtures would be helpful.

Thanks
m

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey



From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Tuesday, March 22, 2016 6:02 PM
To: Freedhoff, Michal (Markey); Black, Jonathan (Tom Udall); Deveny, Adrian (Merkley)
Subject: Sen. Markey TSCA TA request on section 8 nomenclature language

Michal – while understanding the TA request's urgency, given schedules and the specific technical and legal knowledge required on nomenclature, we need to hold off responding fully until Monday. We have concerns about (B)(i) and need more time to articulate them. Please let me know right away if that is a problem.

On statutory mixtures, a concern was raised that the original drafting would have allowed any component of a statutory mixture to get on the TSCA inventory and bypass section 5. What you'll see here are efforts to ensure that the CATEGORIES go onto the inventory but the COMPONENTS (which may include byproducts that do not appear on the TSCA inventory) only get onto the inventory when they're part of the category/mixture but not as separate substances. There are a couple of options here.

Response: Although not able to fully respond yet, we have several concerns, including that the "including, without limitation" language suggests that there are unidentified statutory mixtures beyond the six, creating the possibility that a court might interpret the provision as expanding EPA's current understanding of the scope of statutory mixtures.

The second relates to the multiple CAS question of whether, for example, that language could have been used to argue that all chlorinated paraffins are the same chemical substance. This language seeks to create a clear process by which someone could ask EPA to make the determination, but the determination would be EPA's, Again, pls share thoughts etc.

Response: EPA has no concerns with the (B)(ii) language

We continue to work on this TA request, please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
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Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov>
Sent: Monday, March 21, 2016 7:08 PM
To: Kaiser, Sven-Erik
Cc: Black, Jonathan (Tom Udall)
Subject: Time-sensitive on section 8

Sven

Can you pls rush the review of this redlined text to portions of section 8?

Here are the basic questions:

On statutory mixtures, a concern was raised that the original drafting would have allowed any component of a statutory mixture to get on the tsca inventory and bypass section 5. What you'll see here are efforts to ensure that the CATEGORIES go onto the inventory but the COMPONENTS (which may include biproducts that do not appear on the tsca inventory) only get onto the inventory when they're part of the category/mixture but not as separate substances. There are a couple of options here.

The second relates to the multiple CAS question of whether, for example, that language could have been used to argue that all chlorinated paraffins are the same chemical substance. This language seeks to create a clear process by which someone could ask EPA to make the determination, but the determination would be EPA's, Again, pls share thoughts etc.

I think there is a desire to get this to the House asap.

Thanks
M
Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/3/2016 5:38:45 AM
To: Michal_Freedhoff@markey.senate.gov
Subject: Fwd: Sen. Markey TSCA TA request - House 6(b), may present finding

Michal, TA on House 6(b) "may present" finding. Thanks,
Sven

Does EPA believe that under House 6(b), a determination by the Administrator that a chemical may present an unreasonable risk (and thus be subject to a risk evaluation) would be judicially reviewable?

I asked you this question the other day about a Senate section, I think 5, and your team came back with an answer that said the determination in question seemed to meet a legal test of what an agency action is.

The question is, does the House 6(b) risk finding meet the same test? More generally, the word "determine" confer such standing automatically?

The mere presence of the word "determine" does not establish, as a matter of law, that the action associated with that word is a final agency action under Bennett v. Spear. See, for example,
Fairbanks N. Star Borough v. United States Army Corps of Eng'rs, 543 F.3d 586, 593 (9th Cir. Alaska 2008) (CWA jurisdictional determination by the U.S. Army Corps is not a final agency action reviewable under the APA); Nat'l Ass'n of Home Builders v. United States EPA, 956 F. Supp. 2d 198, 209 (D.D.C. 2013) (holding similarly in District Court for the District of Columbia).

To be a final agency action, the action must meet both prongs of a two part test established by the Supreme Court in Bennet v. Spear.

First, the action in question must mark the "consummation of the agency's decision-making process," and not be "of a merely tentative or interlocutory nature." The "may present an unreasonable risk" determination is not the consummation of the section 6 review process. It merely marks the beginning of the section 6 review process. Further supporting this conclusion, the House bill includes a proviso at 6(b)(6)(C) stating that a determination that a chemical substance "will not present an unreasonable risk of injury" is indeed a final agency action. By reverse implication, the bill thereby supports the view that less positive determinations (e.g., "may present an unreasonable risk of injury") do not amount to final agency actions.

Second, to be a final agency action the action in question must be one by which "rights or obligations have been determined," or from which "legal consequences will flow." While the issuance of a "may present" determination may be the legal pre-requisite of starting the section 6 review process for certain chemicals (i.e., those not requested by industry or on the TSCA workplan), it doesn't actually trigger any preemption of state law or any regulatory restrictions for manufacturers under 6(d). EPA could ultimately end up determining that no regulatory restrictions are needed at all. On these grounds as well as those discussed in the prior paragraph, EPA thinks that there is a strong argument that the "may present" finding under 6(b)(3)(A)(i) is not a final agency action reviewable in court.

From: "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>
Date: February 27, 2016 at 5:47:43 AM EST
To: "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov>
Subject: TA request - House section 6, may present

Sven

Does EPA believe that under House 6(b), a determination by the Administrator that a chemical may present an unreasonable risk (and thus be subject to a risk evaluation) would be judicially reviewable?

I asked you this question the other day about a Senate section, I think 5, and your team came back with an answer that said the determination in question seemed to meet a legal test of what an agency action is.

The question is, does the House 6(b) risk finding meet the same test? More generally, the word "determine" confer such standing automatically?

Thanks

Michal

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/5/2016 9:41:49 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TA on new House section 4
Attachments: Sen. Markey TSCA TA - new House section 4.docx

Michal,
The attached TA responds to the request for high level comments on the new House section 4 (4/4/16 version). Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
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1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Monday, April 04, 2016 11:02 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Fw: Section 4 - the House offer

Sven

I mentioned earlier tonight that the House sent a section 4 offer that I found very concerning. I turned the offer into a redline of tsca in order to illustrate to my colleagues what it would look like.

I don't need detailed TA on this, but would appreciate your high level reaction to it (after section 5, and tomorrow morning is fine).

Thanks
M

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Technical Assistance on new House version (4/4/16) of TSCA Section 4

- In TSCA currently, there is ambiguity as to whether EPA can require testing related to exposure (e.g., monitoring), or only hazard-related testing. This version will retain that ambiguity by retaining current section 4 largely intact, but add ammunition to the argument that EPA can require only hazard-related testing under section 4(a). This is because section 4(a) will continue to authorize EPA to require only "testing", with specification of the health and environmental end points EPA can require testing for, while the new section 4(h) would give EPA arguably more general authority to require "development of information".

- The addition, to the largely unchanged section 4, of section 4(a)(1)(C) – authorizing EPA to require testing by rule as necessary to implement a section 6(a) requirement – may create implementation issues. It is unnecessary, since EPA has clear authority to require testing in section 6(a) rules under section 6(a)(4). In addition, it appears to subject such testing to the general section 4 test requirements and limitations – e.g., the required procedures of section 4(c)(2) – and could therefore be used to argue that EPA has a heightened burden in section 6(a) rules when imposing test requirements, as compared to other section 6(a) requirements.

- We agree with comment MF1 that it is important to authorize EPA to require testing by order as necessary to implement requirements in section 6 rules and section 5 orders.

- We cannot evaluate the scope of testing that EPA is authorized to require by order because we do not have the sections cross-referenced in section 6(h).

- This version of section 4 would provide for certain operational efficiencies and benefits. For example, it does not require EPA to justify issuance of an order to require testing for the purposes specified in 4(h), and it reduces the burden for EPA to justify imposition of animal testing.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/15/2016 11:29:41 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Re: Sen. Markey TSCA TA Request on House Min section 5

Glad to be of service

On Apr 15, 2016, at 7:25 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

This was extremely helpful. Thank you.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

From: Kaiser, Sven-Erik
Sent: Friday, April 15, 2016 5:46 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA Request on House Min section 5

Michal- TA responding to the request on section 5 and low hazard, including attachment.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any questions. Thanks,
Sven

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From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Thursday, April 14, 2016 7:09 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Fw: section 5

I am not sure how much I need this evaluated but big picture thoughts welcome.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/24/2016 4:10:19 PM
To: Michal_Freedhoff@markey.senate.gov; jonathan_black@tomudall.senate.gov; Adrian_Deveny@merkley.senate.gov
Subject: Fwd: Sen. Markey TSCA TA request on House section 8 (4-22)
Attachments: Markey.TSCA TA.Section 8 (4.22).docx; ATT00001.htm

Michal,
This TA responds to the request on house section 8 (4-22).

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
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202-566-2753

RLSO comparison of HLC 4.8 to 4.22

[DISCUSSION DRAFT]

SEC. 8. REPORTING AND RETENTION OF INFORMATION.

(a) IN GENERAL.—Section 8 of the Toxic Substances Control Act (15 U.S.C. 2607) is amended—

(1) in subsection (a)—

(A) in paragraph (1) by striking "The Administrator shall promulgate" and inserting "Not later than 2 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall promulgate or revise";

(B) in paragraph (2), by striking the matter that follows subparagraph (G);

(C) in paragraph (3), by adding at the end the following:

"(C) Not later than 180 days after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, and not less frequently than once every 10 years thereafter, the Administrator, after consultation with the Administrator of the Small Business Administration, shall—

"(i) review the adequacy of the standards pre-

scribed under subparagraph (B); and

"(ii) after providing public notice and an opportunity for comment, make a determination as to whether revision of the standards is warranted."; and

(D) by adding at the end the following:

"(4) CONTENTS.—The rules promulgated pursuant to paragraph (1)—

"(A) may impose differing reporting and ~~record-keeping~~recordkeeping requirements on manufacturers and processors; and

"(B) shall include the level of detail necessary to be reported, including the manner by which use and exposure information may be reported.

"(5) ADMINISTRATION.—In carrying out this section, the Administrator shall, to the extent feasible—

"(A) not require reporting which is unnecessary or duplicative;

"(B) minimize the cost of compliance with this section and the rules issued thereunder on small manufacturers and processors; and

"(C) apply any reporting obligations to those persons likely to have information rel-

evant to the effective implementation of this title.

"(6) NEGOTIATED RULEMAKING.—(A) The Administrator shall enter into a negotiated rulemaking pursuant to subchapter III of chapter 5 of title 5, United States Code, to develop and publish, not later than 2 years ?after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, a proposed rule providing for limiting reporting for any inorganic byproducts which are subsequently recycled, reused, or reprocessed, including by any other person.

"(B) Not later than 3 and one-half years after such date of enactment, the Administrator shall publish a final rule resulting from such negotiated rulemaking."; and

(2) in subsection (b), by adding at the end the following:

"(3) NOMENCLATURE.—

Commented [A1]: EPA TA:
** NEW OBSERVATION**
We understand what this is probably intended to accomplish: limit the reporting obligations of the manufacturers of inorganic byproducts under the CDR, in the case where such byproducts are subsequently recycled, reused, or reprocessed – specifically including the scenario where such recycling/reuse/reprocessing is not done by the original byproduct manufacturer. The current drafting, however, is overbroad, and could lead to confusion about the scope of the rulemaking.

- "Limiting reporting" → As drafted this could limit reporting under 8(a), 8(b), 8(c), 8(d), and 8(e), whereas the intent was probably just to cover CDR reporting, which is under 8(a).
- "reporting for" → This could lead to arguments that that non-byproduct chemicals manufactured out of the byproducts needn't be reported either, on the grounds that that is also "reporting for" the byproduct. The CDR obligation at issue the duty of the byproduct manufacturer to report its own manufacture of the byproduct, when that manufacturer it is not channeling the byproduct into commerce except for recycling/reuse/reprocessing purposes. ??
- "any" → This word suggests that EPA lacks authority to consider whether certain of these byproducts should not have limited reporting (e.g., based on particular hazard concerns) ??.
- "by any other person" → The placement of this phrase creates ambiguity about whether we are just talking about reporting by the byproduct manufacturer or also reporting by the recycler who manufactures other stuff from the byproduct. We presume you just mean the latter.

Suggested redraft to address all of these issues:

"a proposed rule providing for limiting the reporting requirements, under this subsection, of manufacturers of [any] inorganic byproducts, when such byproducts, whether by the byproduct manufacturer or by any other person, are subsequently recycled, reused, or reprocessed."

"(A) IN GENERAL.—In carrying out paragraph (1), the Administrator shall—

"(i) maintain the use of Class 2 nomenclature in use on the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act;

"(ii) maintain the use of the Soap and Detergent Association Nomenclature System, published in March 1978 by the Administrator in section 1 of addendum III of the document entitled 'Candidate List of Chemical Substances', and further described in appendix A of volume I of the 1985 edition of the Toxic Substances Control Act Substances Inventory (EPA Document No. EPA–560/7–85–002a); and

"(iii) treat all chemical substances described by the following category listings, when

manufactured as described in such ~~mixtures~~ appendix, as being included on the list ~~established~~ published under paragraph (1) under the Chemical Abstracts Service numbers for the respective categories, ~~including ¿:~~

~~ϕ"(iii) ϕalternative clause (iii) text:¿~~

~~include on the list established under paragraph (1), under the Chemical Abstracts Service numbers for the respective categories, ϕthe combinations considered to be statutory mixtures under this Act¿, and their ϕcomponents¿ when present in such mixtures, including ¿~~

ϕ"(I) ~~cement,~~ Cement, Portland, chemicals, CAS No. 65997–15–1~~;¿~~.

~~ϕ~~

"(II) ~~cement,~~ Cement, alumina, chemicals, CAS No. 65997–16–2~~;~~.

~~(3)~~ "(III) ~~glass~~Glass, oxide, chemicals, CAS No. 65997–17–3~~;~~.

~~(4)~~ "(IV) ~~frits~~Frits, chemicals, CAS No. 65997–18–4~~;~~.

~~(5)~~ "(V) ~~steel~~Steel manufacture, chemicals, CAS No. 65997–19–5~~; and~~.

~~(6)~~ "(VI) ~~ceramic~~Ceramic materials and wares, chemicals, CAS No. 66402–68–4~~.~~.

"(B) MULTIPLE NOMENCLATURE CONVENTIONS.—

"(i) IN GENERAL.—With respect toThe Administrator multiple nomenclature conventions, the Administrator shall—

"(I) maintain the nomenclature conventions for chemical substances and mixtures; and

"(II) develop new guidance that—

"(aa) establishes equivalency between the nomenclature conventions for chemical substances on the list published under paragraphpara-graph (1); and

Commented [A2]: EPA TA: For reasons previously described in prior TA, 8(b)(3)(B) is problematic, and the savings clauses in 8(b)(3)(C) are ineffective to solve the problems created here.

"(bb) permits persons to rely on the new guidance for purposes of determining whether a chemical substance is on the list published under paragraph (1)~~(c)~~.

~~(ii)~~ "(ii) MULTIPLE CAS NUMBERS.—For ~~Upon request by a manufacturer or processor, the Administrator shall determine~~ whether a chemical substance ~~appears mul~~determined by the ~~tiple~~Administrator to appear multiple times on ~~the list published under~~

the list in paragraph (1) under different

~~Chemical~~

Abstracts Service numbers, ~~and, if so,~~ the

Administrator shall ~~recognize~~develop guidance rec-

~~ognizing~~ the multiple

listings as a single

chemical substance.~~¿~~

~~¶"(iii) TITLE.—If a manufacturer or processor makes a request under clause (ii), the Administrator shall make the determination not later than 30 days after the date of the request.¿~~

~~¶"(C) EFFECT OF PARAGRAPH.—Nothing in this paragraph exempts a chemical substance from the requirements of section~~RELATIONSHIP TO SECTION 5.~~¿~~

~~¶"(C) *ALTERNATE*: EFFECT OF PARAGRAPH.—Notwithstanding~~"(i) CHEMICAL SUBSTANCES DE-

SCRIBED BY CATEGORIES.—Notwithstanding subparagraph (A)~~(iii),~~, a chemical substance that is ~~a compo-~~

~~nent of a mixture ¶identified /~~ -described~~?¿~~ by a category

~~¶'identified' makes it sound like it might only~~

~~*refer to the* listed *ones, but the list reads as non-*~~

~~*exclusive. 'described' is better if intent is to cover*~~

~~*everything, not just the listed ones;*~~ ~~in subpara-~~

~~graph~~ subparagraph (A)(iii)~~,~~ shall~~,~~ be ~~subject to the require-~~

~~ments of~~subject to section 5 ~~when not present in such~~if the chemical sub-

~~mixture, if such~~ stance is not included as an individual

chemical substance on the list published under paragraph (1) as of the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

"(ii) CHEMICAL SUBSTANCES GROUPED BY CAS NUMBER.—Notwithstanding subparagraph (B), a chemical substance that is not ~~in~~included as an individual chemical substance on the list ~~established~~published under paragraph (1) as of the date

~~(1) other than as a component of such a mixture;~~

of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act shall be subject to section 5.

"(4) CHEMICAL SUBSTANCES IN COMMERCE.—

"(A) RULES.—

"(i) IN GENERAL.—Not later than 1 year after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator, by rule, shall require manufacturers, and may require processors, subject to the limitations under subsection (a)(5)(A), to notify the Administrator, by not later than 180 days after the date on which the final rule is published in the Federal Register, of each chemical substance on the list published under paragraph (1) that the manufacturer or processor, as applicable, has manufactured or processed for a non-

exempt commercial purpose during the 10-year period ending on the day before the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

"(ii) ACTIVE SUBSTANCES.—The Administrator shall designate chemical sub-

stances for which notices are received under clause (i) to be active substances on the list published under paragraph (1).

"(iii) INACTIVE SUBSTANCES.—The Administrator shall designate chemical substances for which no notices are received under clause (i) to be inactive substances on the list published under paragraph (1).

"(iv) LIMITATION.—No ~~chemical~~ chemical substance ~~substance~~ on the list published under paragraph (1) shall be removed from such list by reason of the implementation of this subparagraph, or be subject to section 5 by reason of a change to active status under paragraph (5)(B).

Commented [A3]: EPA TA
**** NEW OBSERVATION ****
Consider making this citation more specific -- to 5(a)(1)(A)(i). This would limit the impact of the provision to new chemical review, rather than significant new use rulemaking. It may be reasonable to SNUR a previously "dead" chemical that gets moved to the active list. This is consistent with TA we had on the savings clauses for nomenclature re the imprecision and potential breadth of "subject to section 5".

ø"(B) CONFIDENTIAL CHEMICAL SUBSTANCES.—In promulgating a rule under subparagraph (A), the Administrator shall—~~ø~~need—¿

~~1 to harmonize with sec 14¿¿~~

ø"(i) maintain the list under paragraph (1), which shall include a confidential portion and a nonconfidential portion consistent with this section and section ~~258~~ 14;¿

"(ii) require any manufacturer or processor of a chemical substance on the confidential portion of the list published under paragraph (1) that seeks to maintain an existing claim for protection against disclosure of the specific ~~identity of~~chemical identity of the chemical substance as ~~confidential pur~~con~~suant~~fidential pursuant to section 14 to submit ~~a notice~~ under subparagraph (A) that ~~includes~~in~~cludes~~ such request;¿

"(iii) require the substantiation of those claims pursuant to section 14 and in accordance with the review plan described in subparagraph (C); and¿

"(iv) move any active chemical substance for which no request was received to maintain an existing claim for protection

against disclosure of the specific chemical identity of the chemical substance as ~~confidential~~ confidential from the confidential portion of the list published under paragraph (1) to the ~~non-confidential~~nonconfidential portion of that list.¿

"(C) REVIEW PLAN.—Not later than 1 year after the date on which the Administrator compiles the initial list of active substances pur-

suant to subparagraph (A), the Administrator shall promulgate a rule that establishes a plan to review all claims to protect the specific ~~iden~~chem~~tities~~ical identities of chemical substances on the ~~confidential~~ portion of the list published under ~~paragraph~~ (1) that are asserted pursuant to subparagraph (B).

~~(B). ø need to harmonize with sec 14¿~~

"(D) REQUIREMENTS OF REVIEW PLAN.—

~~øIn~~In establishing~~¿~~ the review plan under ~~sub~~subpara~~paragraph~~graph (C), the Administrator shall—~~ø need to harmonize with sec 14¿~~

"(i) require~~ø~~, at the time requested by the Administrator,~~¿~~ all manufacturers or processors asserting claims under subparagraph (B) to substantiate the claim ~~unless~~, in accordance with section 14, unless the ~~manufacturer~~manufacturer or processor has ~~substantiated~~substantiated the claim in a submission made to the ~~Administrator~~Admin-

istrator during the 5-year ~~period~~

~~riod~~period ending on

the date of the request by the Adminis-

~~the Administrator~~trator; and

"(ii) in accordance with section 14—

"(I) review each substantiation—

"(aa) submitted pursuant to

clause (i) to determine if the

claim ~~warrants~~ qualifies for protection from disclosure; and

"(bb) submitted previously by a manufacturer or processor and relied on in lieu of the substantiation required pursuant to clause (i), if the substantiation has not been previously reviewed by the Administrator, to determine if the claim warrants protection from disclosure;

"(II) approve, approve in part, ~~or~~ and deny in part, or deny each claim; and

"(III) except as provided in this section and section 14, protect from disclosure information for which the Administrator approves such a claim

for a period of 10 years, unless, prior to the expiration of the period—

"(aa) the person notifies the Administrator that the person is withdrawing the claim, in which case ~~the Administrator shall not promptly make~~ protect the information from disclosure; ~~available to the public;~~ or

"(bb) the Administrator otherwise becomes aware that the ~~need~~information does not qualify for protection ~~from disclosure can no longer be substantiated,~~ disclosure, in ~~which case the Administrator~~ which the Administrator shall take ~~ϕthe~~the actions described in section 14(g)(2)~~ϕ~~.

~~ϕneed to harmonize with sec 14ϕ~~.

"(E) TIMELINE FOR COMPLETION OF REVIEWS.—~~ϕneed to harmonize with sec 14ϕ~~

"(i) IN GENERAL.—The Administrator shall implement the review plan so as to complete reviews of all claims specified in subparagraph (C) not later than 5 years after the date on which the Administrator ~~ϕcompiles;~~compiles the initial list of active ~~substances~~ substances pursuant to subparagraph (A).

"(ii) CONSIDERATIONS.—

"(I) IN GENERAL.—The Administrator may extend the deadline for completion of the reviews for not more than 2 additional ~~years~~, years, after an ~~adequate~~ adequate public justification, if the ~~Administrator~~ Administrator determines that the ~~extension~~ extension is necessary based on the

number of claims needing review and the available resources.

"(II) ANNUAL REVIEW GOAL AND RESULTS.—At the beginning of each year, the Administrator shall publish an annual goal for reviews and the number of reviews completed in the prior year.

"(5) ACTIVE AND INACTIVE SUBSTANCES.—

"(A) IN GENERAL.—The Administrator shall keep designations of active substances and inactive substances on the list published under paragraph (1) current.

"(B) CHANGE TO ACTIVE STATUS.—

"(i) IN GENERAL.—Any person that intends to manufacture or process for a nonexempt commercial purpose a chemical substance that is designated as an inactive

substance shall notify the Administrator before the date on which the inactive substance is manufactured or processed.

"(ii) CONFIDENTIAL CHEMICAL IDENTITY.—If a person submitting a notice under clause (i) for an inactive substance on the confidential portion of the list pub-

lished under paragraph (1) seeks to maintain an existing claim for protection against disclosure of the specific ~~identity of~~chemical identity of the inactive substance as ~~confidential~~confidential, the person shall, consistent with the requirements of section 14—

"(I) in the notice submitted under clause (i), assert the claim ~~consistent with the requirements of section 14;~~; and

"(II) by not later than 30 days after providing the notice under clause (i), substantiate the claim.

"(iii) ACTIVE STATUS.—On receiving a notification under clause (i), the Administrator shall—

"(I) designate the applicable chemical substance as an active substance;

"(II) pursuant to section 14, promptly review any claim and associated substantiation submitted pursuant to clause (ii) for protection against disclosure of the specific ~~identity~~chemical identity of the chemical ~~substance~~substance and ~~ap-~~

~~prove~~approve, approve in part and deny in part, or deny the claim;

"(III) except as provided in this section and section 14, protect from disclosure the specific ~~identity of the~~chemical identity of the chemical substance for which the ~~Administrator~~Administrator approves a claim under subclause (II) for a ~~period~~ period of 10 years, unless, prior to the expiration of the period—

"(aa) the person notifies the Administrator that the person is withdrawing the claim, in which case the Administrator shall ~~not promptly make~~protect the information ~~available to the public~~from disclosure; or

"(bb) the Administrator otherwise becomes aware that the ~~need~~information does not qualify for

protection from disclosure can no longer be substantiated, disclosure in which case the Administrator shall take the actions described in section 14(g)(2); and

"(IV) pursuant to ~~øsection 4A / prioritization - need to harmonize with~~ section 6~~¿~~, ~~(b),~~ review the priority of the chemical substance as the ~~Adminis~~Administrator deter~~trator determines~~mines to be necessary.

"(C) CATEGORY STATUS.—The list of inactive substances shall not be considered to be a category for purposes of section 26(c).

"(6) INTERIM LIST OF ACTIVE SUBSTANCES.—Prior to the promulgation of the rule required under paragraph (4)(A), the Administrator shall designate the chemical substances reported under part 711 of title 40, Code of Federal Regulations (as in effect on the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act), during the reporting period that most closely preceded the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, as the interim list of active substances for the purposes of ~~øsection 4A / prioritization¿~~. section 6(b).

"(7) PUBLIC INFORMATION.—Subject to this subsection ¢and section 14¿, the Administrator shall make available to the public—

"(A) ~~the~~each specific chemical identity ~~of each chemical substance~~ on the nonconfidential portion of the list published under paragraph (1);

"(B) the ~~ø~~unique identifier assigned under section 14,¿ accession number, generic name, and, if applicable, premanufacture notice case number for each chemical substance on the confidential portion of the list published under paragraph (1) for which a claim of confidentiality was received; and

"(C) the specific chemical identity of any ~~active substance~~active substance for which—

"(i) a claim for protection against disclosure of the specific chemical identity of the active substance was not asserted, as required under this subsection or section 14;

~~ø~~"(ii) all claims for protection against disclosure of the specific chemical identity of the ~~active~~active substance have been denied

by the ~~Ad-~~
~~ministrator~~Administrator; or~~;~~

"(iii) the time period for protection against disclosure of the specific chemical identity of the active substance has ~~expired~~expired.

"(8) LIMITATION.—No person may assert a new claim under this subsection ~~or~~or section 14~~,~~ for protection from disclosure of a specific chemical identity of

any active or inactive substance for which a notice is received under paragraph (4)(A)(i) or (5)(B)(i) that is not on the confidential portion of the list published under paragraph (1).

"(9) CERTIFICATION.—Under the rules promulgated under this subsection, manufacturers ϕand processors, as applicable,¿ shall be required—

"(A) to certify that each notice or substantiation the manufacturer or processor submits complies with the requirements of the rule, and that any confidentiality claims are true and correct; and

"(B) to retain a record ϕdocumenting compliance with the rule and supporting confidentiality claims¿ for a period of 5 years beginning on the last day of the submission period.".

(b) MERCURY INVENTORY.—Section 8(b) of the Toxic Substances Control Act (15 U.S.C. 2607(b)) (as

Commented [A4]: This appears to be identical to language on mercury that EPA has already supplied TA on, in a separate section. We are therefore not reiterating that prior TA here.

amended by subsection (a)) is further amended by adding at the end the following:

"(10) MERCURY.—

"(A) DEFINITION OF MERCURY.—In this paragraph, notwithstanding section 3(2)(B), the term 'mercury' means—

"(i) elemental mercury; and

"(ii) a mercury compound.

"(B) PUBLICATION.—Not later than April 1, 2017, and every 3 years thereafter, the Administrator shall carry out and publish in the Federal Register an inventory of mercury supply, use, and trade in the United States.

"(C) PROCESS.—In carrying out the inventory under subparagraph (B), the Administrator shall—

"(i) identify any manufacturing processes or products that intentionally add mercury; and

"(ii) recommend actions, including proposed revisions of Federal law or regulations, to achieve further reductions in mercury use.

"(D) REPORTING.—

"(i) IN GENERAL.—To assist in the preparation of the inventory under subparagraph (B), any person who manufactures mercury or mercury-added products or otherwise intentionally uses mercury in a manufacturing process shall make periodic reports to the Administrator, at such time and including such information as the Administrator shall determine by rule promulgated not later than 2 years after the date of enactment of this paragraph.

"(ii) COORDINATION.—To avoid duplication, the Administrator shall coordinate the reporting under this subparagraph with the Interstate Mercury Education and Reduction Clearinghouse and any applicable reporting requirements under the Solid Waste Disposal Act.

"(iii) EXEMPTION.—Clause (i) shall not apply to a person engaged in the generation, handling, or management of mercury-containing waste, unless that person manufactures or recovers mercury in the management of that waste.".

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/13/2016 9:22:32 PM
To: 'Black, Jonathan (Tom Udall)' [Jonathan_Black@tomudall.senate.gov]
Subject: Sen. Udall TSCA TA request on Industry nominated chemicals
Attachments: Udall.TSCA TA.Section 6(b)(4)(E).docx

Jonathan,
The attached TA responds to the request on industry nominated chemicals.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Tuesday, April 12, 2016 6:19 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: FW: Sen. Udall TSCA TA request on Industry nominated chemicals

Would appreciate thoughts on these edits/suggestions from EDF

Attached see our additions to EPA's rewrite of section 6(b)(4)(E), which:

- Include consistently missed deadlines for risk evaluations and rules as an additional critical indicator of EPA being overrun by industry requests;
- Preclude EPA from allocating disproportionately more resources to industry-requested chemicals, a concept that is already in the current text; and
- Require EPA, when selecting among industry requests, to give preference to those presenting greater concern using the criteria specified in the prioritization section.

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Tuesday, April 12, 2016 2:02 PM
To: Richard Denison; Joanna (joannaslaney@gmail.com)
Subject: FW: Sen. Udall TSCA TA request on Industry nominated chemicals

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Monday, April 11, 2016 5:20 PM
To: Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>
Subject: Sen. Udall TSCA TA request on Industry nominated chemicals

Jonathan,
This TA responds to the request on industry nominated chemicals language.

You requested a replacement for (b)(4)(E) that would eliminate the industry cap, but nonetheless provide comparable assurance that industry prioritizations would not overrun the resources necessary for EPA priorities.

We believe the following replacement for (E)(i) and (ii) would accomplish this objective. It operates by simply shutting down the pipeline for taking further industry requests if EPA falls behind on the expected pace of pursuing its own priorities. The edits are also attached as a redline to section 6 (attached).

(E) LIMITATION AND CRITERIA

"(i) If the Administrator's designation of priority substances or conduct of risk evaluations is insufficient to satisfy the requirements of paragraph (2)(A), (2)(B), or (2)(C), then the Administrator shall accept no further requests under subparagraph (C)(ii) until the requirements of paragraph (2)(A), (2)(B), and (2)(C) are all satisfied.

(ii) Requests for risk evaluations under subparagraph (C)(ii) shall be subject to public notice and comment and to the payment of fees pursuant to section 26(b)(3)(D), and the Administrator shall not expedite or otherwise provide special treatment to such risk evaluations,

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Monday, April 11, 2016 1:44 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Re: Sen. Udall TSCA TA request on Industry nominated chemicals

Thanks Sven, I should have asked for you to draft to the Senate offer.

Possible to see that? Sorry.

Sent from my BlackBerry 10 smartphone on the Verizon Wireless 4G LTE network.

From: Kaiser, Sven-Erik
Sent: Monday, April 11, 2016 1:33 PM
To: Black, Jonathan (Tom Udall)
Subject: Sen. Udall TSCA TA request on Industry nominated chemicals

Jonathan,
This TA responds to the request on industry nominated chemicals.

QUESTION: EPA has indicated that the House bill allows industry nominated chemicals to overwhelm EPA's priorities.

Is there a way to draft the house bill/proposal to allow for industry nominated chemicals to move through "without a cap" (as per the senate bill), but also without compromising EPA's priorities?

Response:
The language in question is for the House offer. It would also work with minor adjustment for the House bill as passed. There is no min/max provision in the House bill as passed, so that part has to be deleted if you are modifying the House bill as passed.

House offer

6(b)(7) MINIMUM NUMBER.--

(A) IN GENERAL.-- Subject to the availability of appropriations, the Administrator shall initiate 10 or more risk evaluations under paragraph (3)(A)(i) or (3)(B) in each fiscal year beginning in the fiscal year of the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

(B) LIMITATION.-- Notwithstanding any other provision of this section, if the Administrator does not initiate 10 or more risk evaluations under (A) in any complete fiscal year following the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, then in the following fiscal year the Administrator shall not accept any requests under paragraph (3)(A)(ii) and is not subject to paragraph (3)(C)(i)(I), unless in that fiscal year the Administrator has first initiated 10 risk evaluations under (A).

House bill as passed

6(b)(7) MINIMUM NUMBER.--

(A) IN GENERAL.-- Subject to the availability of appropriations, the Administrator shall initiate 10 or more risk evaluations under paragraph (3)(A)(i) or (3)(B) in each fiscal year beginning in the fiscal year of the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

(B) LIMITATION.-- Notwithstanding any other provision of this section, if the Administrator does not initiate 10 or more risk evaluations under (A) in any complete fiscal year following the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, then in the following fiscal year the Administrator shall not accept any requests under paragraph (3)(A)(ii) unless in that fiscal year the Administrator has first initiated 10 risk evaluations under (A).

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any additional questions. Thanks,

Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: "Black, Jonathan (Tom Udall)" <Jonathan_Black@tomudall.senate.gov>
Date: April 10, 2016 at 6:07:41 PM EDT
To: "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov>
Subject: Industry nominated chemicals

Hi Sven,

EPA has indicated that the House bill allows industry nominated chemicals to overwhelm EPA's priorities.

Is there a way to draft the house bill/proposal to allow for industry nominated chemicals to move through "without a cap" (as per the senate bill), but also without compromising EPA's priorities?

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/29/2016 3:37:16 PM
To: Couri, Jerry [JerryCouri@mail.house.gov]
Subject: Re: HEC TSCA TA request on TSCA section 5

Got it- checking

On Apr 29, 2016, at 11:32 AM, Couri, Jerry <JerryCouri@mail.house.gov> wrote:

Before we come to a decision on later today, I have a simple question from the TA on the definition of 'applicable review period' on Page 29:

The TA suggested that the 'applicable review period' might end on a date "as is provided for in subsection (b)". Unless I am missing something, I don't read an explicit extension in section 5(b). How does section 5(b) create this extension?

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Friday, April 29, 2016 10:44 AM
To: Couri, Jerry
Subject: Re: HEC TSCA TA request on TSCA section 5

Jerry- I misunderstood our availability. The attorney on this is only available until 3. Any chance 2 or 2:30 works?
Apologies,
Sven

On Apr 29, 2016, at 10:30 AM, Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov> wrote:

Jerry, Okay- let's aim for 3pm - 866-299-3188, code 202-564-2910#. Just let me know if your schedule changes as we can push it back if needed. Thanks,
Sven

On Apr 29, 2016, at 10:28 AM, Couri, Jerry <JerryCouri@mail.house.gov> wrote:

OK. Thanks. Likely 3p is better.

Sent from my BlackBerry 10 smartphone on the Verizon Wireless 4G LTE network.

From: Kaiser, Sven-Erik
Sent: Friday, April 29, 2016 10:26 AM
To: Couri, Jerry
Subject: HEC TSCA TA request on TSCA section 5

Jerry - are you available for a clarifying call at 11am or after 3pm?

We think you are asking whether -- if changes are made to 5a3B so it aligns with the current trigger language for 5(e) (rather than conforming the trigger language for 5(e) to the new 5a3B -- that would obviate the need for some or all of the other suggested changes in 5e. We think the answer is no. Most or all of the other changes have to do with converting 5e from a blocking provision to an enabling provision and are not impacted by the specific trigger.
Thanks,
Sven

On Apr 29, 2016, at 9:45 AM, Couri, Jerry <JerryCouri@mail.house.gov> wrote:

Part of it relates to whether putting 5(e)(1)(A) into 5(a)(3)(B), what would be the effect of not changing 5(e) further and if change necessary, how much of the previous TA stands?

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Thursday, April 28, 2016 8:55 PM
To: Couri, Jerry
Subject: Re: TA request on TSCA section 5

Jerry,
This TA responds to the request on section 5(e).

We sent suggested changes both to the new 5(a)(3)(B) (to align with 5(e)) and to 5(e)(1)(A) (e.g., to remove the language about substantial production, release and exposure, which is not part of the 5(a)(3)(B) finding under your draft). Do you have specific questions about the changes we suggested to the lead in to 5(e)? See attachments for the most recent section 5 TA.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

On Apr 28, 2016, at 5:53 PM, Couri, Jerry <JerryCouri@mail.house.gov> wrote:

Sven:

Thanks to you and the folks at EPA for the TA on section 5. We have a follow-up question on what you sent to us:

If we change the wording in proposed new section 5(a)(3)(B) to match existing section 5(e) -- as I think the Agency's TA suggests, would we need to change the lead in to existing 5(e)?

Thanks.

- Jerry

Gerald S. Couri
Senior Environmental Policy Advisor | Committee on Energy and Commerce
U.S. House of Representatives

2125 Rayburn Building | 202.226.9603 (direct)

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/17/2016 6:28:45 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: RE: TSCA TA - Section 6 Issue

checking

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Thursday, March 17, 2016 2:21 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Re: TSCA TA - Section 6 Issue

Question - what about our section 26 language

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

From: Kaiser, Sven-Erik
Sent: Thursday, March 17, 2016 2:10 PM
To: Freedhoff, Michal (Markey)
Subject: TSCA TA - Section 6 Issue

Michal,
In reviewing bill text (house and senate passed bills), EPA just discovered a technical issue that will have significant policy implications for EPA's ongoing work under Section 6. As currently drafted, both Senate and House bills could frustrate EPA's ability to timely manage risks that have been (or may be) identified in our current Work Plan risk assessments.

As you know, EPA has been working on risk assessments (draft and final) for a number of chemical substances - TCE, NMP, MC, and 1-BP. These risk assessments have been scoped relatively narrowly, so as to focus the Agency's resources on uses most likely to present risk. EPA is *not* looking at all the conditions of use for these chemicals.

This approach, which might be characterized as a *partial* risk evaluation or *partial* safety determination, we see as simply not contemplated under the Senate and House bills. The section 6 structure in both bills would require EPA to assess a chemical in its entirety, based on all conditions of use – not just a subset of those uses.

Should the House/Senate construct become law, the Agency would be left with a difficult choice in moving forward with our ongoing Work Plan assessment and rules.

One option might be to move forward with finalizing the risk evaluation and regulating a subset of chemical uses. There's some risk that the new law would not support such an interpretation. Even if it would, the risk management deadline for the chemical would start ticking immediately. That means that EPA would be on the clock to expand the risk evaluation to cover remaining non-scoped uses, finalize those determinations, AND complete a rulemaking to manage any associated risks. For risk assessments that are draft or final, this appears to be the public

policy preferred option. It's highly unlikely that EPA would be able to complete this work for non-scoped uses within the statutory timeframes.

Alternatively, EPA could hold off on moving to risk management finalizing and spend additional time evaluating the full suite of uses. This would have the practical effect of allowing known risks to health or the environment (i.e., those identified in the narrowly-scoped assessment) to continue unregulated during this period.

We'd welcome an opportunity to work with you on a drafting solution to this issue, but wanted to bring to your attention as soon as possible.

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 12/8/2016 6:45:57 PM
To: Cohen, Jacqueline [jackie.cohen@mail.house.gov]
Subject: HEC Inquiry on TSCA PMNs

Jacqueline,
Thanks for the request on PMN outputs.

New valid PMNs, MCANs and SNUNs received since June 23 (as of Dec. 6):	164
"Re-set" valid PMNs and MCANs in process as of June 22:	233
TOTAL valid cases reviewed:	397

Since June 22, 25 of these cases have been withdrawn and 54 have had final EPA determinations that the chemical is "not likely to present an unreasonable risk" of injury to health or the environment.

For 254 cases, EPA made interim determinations that the chemical "may present an unreasonable risk" for the intended and/or reasonably foreseen uses (Section 5(a)(3)(B)(ii)(I)). 53 of these were "may present an unreasonable risk" for only reasonably foreseen uses.

It is anticipated that once final determinations are made, EPA will issue section 5(e) orders for these PMNs which place conditions on their manufacture, processing, distribution or use and may require testing for toxicity or environmental fate, among other things. These determinations are not final until the order is written and signed.

In addition, please note that in response to the request, the numbers provided above only reflect interim determinations of "may present an unreasonable risk." The Agency also intends to issue section 5(e) orders for cases where the final determination is "insufficient information" under section 5(a)(3)(B)(i) and for cases with "exposure-based" determinations under section 5(a)(3)(B)(ii)(II).

Also, an additional 250 cases are still in the review process. Interim determinations have not yet been made for these cases.

Please let me know if any additional questions. The congressional staff briefing on Mon, Dec 12 at 2pm in 406 Dirksen provides an additional opportunity to discuss your questions and the New Chemicals Review program.
Best,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Cohen, Jacqueline [mailto:jackie.cohen@mail.house.gov]
Sent: Friday, October 28, 2016 3:54 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: PMN through rate so far?

Sven,

Do you have a sense of how many PMN's have been reviewed since the changes took effect, and what number were found to meet the threshold of "may present" an unreasonable risk?

Jacqueline G. Cohen
Senior Counsel
Committee on Energy and Commerce, Democratic Staff
U.S. House of Representatives
jacqueline.cohen@mail.house.gov
202-225-4407

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/20/2016 1:42:19 AM
To: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
Subject: Re: Sen. Udall TSCA TA on Mixed confidential section

Got it- will include that with the request

On Apr 19, 2016, at 9:39 PM, Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov> wrote:

Also: what would be lost, if anything, by deleting this paragraph?

Sent from my BlackBerry 10 smartphone on the Verizon Wireless 4G LTE network.

From: Kaiser, Sven-Erik
Sent: Tuesday, April 19, 2016 9:35 PM
To: Black, Jonathan (Tom Udall)
Subject: Sen. Udall TSCA TA on Mixed confidential section

Jonathan,
Got it - checking. Thanks,
Sven

On Apr 19, 2016, at 9:30 PM, Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov> wrote:

Can we get epa TA drafting assistance on HLC's section 14,

14(b)(1) the mixed confidential section?

we'd like to see how you would do it?

Sent from my BlackBerry 10 smartphone on the Verizon Wireless 4G LTE network.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/3/2016 5:34:18 AM
To: Michal_Freedhoff@markey.senate.gov
Subject: Fwd: New Followup - Sen. Markey TSCA TA request on section 5 PBTs

Michal- TA on section 5 PBTs. Thanks,
Sven

I was responding to your earlier TA that I attached with the incoming question that said your current PBT policy from 1999 leads to more restrictive risk management than the 697 language. In thinking about a concern raised by an external stakeholder that applying a tsca workplan methods document to new chemicals may not make sense, I wondered if there was a way to strengthen the section 5 PBT provision by referencing the 1999 policy instead of the 2012 scoring document and maximum practicable.

Does that help you frame some drafting options?

As you point out, we said in earlier TA that "application of the New Chemical PBT policy. . . is likely to be more stringent than the risk management standard included in the Senate PBT provision -- 'reduce exposure to the maximum extent practicable'". On further reflection, we no longer believe this is true.

The Senate PBT new chemicals standard is not to reduce exposure to the maximum extent practicable; rather, it is to ensure the chemical is likely to meet the safety standard AND, IN ADDITION, to reduce exposure to the maximum extent practicable. Although TSCA section 5(e) does not contain an explicit standard for the restrictions EPA can impose through orders, we believe it is best interpreted as implicitly limiting the restrictions to those that are reasonably necessary to address the risk concerns that led EPA to conclude the chemical may present an unreasonable risk, and EPA has implemented section 5(e) with that understanding. The reason EPA in the new chemical PBT guidance prescribed ban pending upfront testing as the general response for new chemicals that exceed the upper threshold for persistence or bioaccumulation is that EPA believes such a restriction is generally necessary to protect against the potential unreasonable risk, given the uncertainty as to the impacts of the manufacture, processing and use of such chemicals, even at low levels, over time. We believe the same logic would lead to the conclusion that a ban pending upfront testing is necessary to ensure a new PBT chemical meeting one of these thresholds is likely to meet the safety standard under S 697.

Moreover, because a new chemical by definition has not been commercialized, EPA believes a ban pending upfront testing would generally be practicable, even if the exposure reduction provision were applicable.

We do not share the stakeholder's concerns regarding the applicability of the 2012 Workplan Methods Document in the new chemicals context. The reference in 5(d)(4)(D) of 697 requires EPA to apply only the portion of the 2012 Methods document related to identifying P, B, and T characteristics of a chemical, and we believe this process is equally applicable and appropriate for both new and existing chemicals.

Let us know if you would still like assistance in drafting language options to achieve a certain policy objective.

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Wednesday, March 02, 2016 10:30 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Re: Sen. Markey TSCA TA request on section 5 PBTs

Thanks

I was responding to your earlier TA that I attached with the incoming question that said your current PBT policy from 1999 leads to more restrictive risk management than the 697 language. In thinking about a concern raised by an external stakeholder that applying a tsca workplan methods document to new chemicals may not make sense, I wondered if there was a way to strengthen the section 5 PBT provision by referencing the 1999 policy instead of the 2012 scoring document and maximum practicable.

Does that help you frame some drafting options?

Thanks
Michal

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

From: Kaiser, Sven-Erik
Sent: Wednesday, March 2, 2016 10:23 AM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA request on section 5 PBTs

Michal – please see the attached document in response to your TA request on PBTs. Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Monday, February 29, 2016 1:59 PM

To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Markey TSCA TA PBTs on New Chemicals

Sven:

Wanted to confirm EPA views of a proposed change to section 5 PBT language following on this older TA. Is the new alternative likely to result in a more stringent outcome than S 697? If not, can you suggest a tweak?
Thanks
Michal

Proposing to change from

D) PERSISTENT AND BIOACCUMULATIVE SUBSTANCES.—For a chemical substance the Administrator determines, with respect to persistence and bioaccumulation, scores high for 1 and either high or moderate for the other, pursuant to the TSCA Work Plan Chemicals Methods Document published by the Administrator in February 2012 (or a successor Methods Document), the Administrator shall, in selecting among prohibitions and other restrictions that the Administrator determines are sufficient to ensure that the chemical substance is not likely to present an unreasonable risk of injury to health or the environment, reduce potential exposure to the substance to the maximum extent practicable.

To

D) PERSISTENT AND BIOACCUMULATIVE SUBSTANCES.—In selecting among prohibitions and other restrictions for a chemical substance that is a persistent and bioaccumulative substance, the Administrator shall act in a manner consistent with the TSCA Policy Statement on Persistent, Bioaccumulative and Toxic New Chemical Substances published by the Administrator in November 1999 (or a successor Policy Statement).

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey

<image001.png><image002.png> <image004.jpg>

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Thursday, December 03, 2015 7:20 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA PBTs on New Chemicals

Michal,
This responds to your TA request on new chemical reviews. Please let me know if any additional questions Thanks,
Sven

Question: If EPA WAS told to score new chemicals using TSCA methods document criteria, a) would EPA have enough information on the new chemical to do so, and b) how long would scoring take (days, weeks, months, etc?)

a) **Yes, EPA would be able to score new chemicals in the same way it scores chemicals pursuant the TSCA Work Plan Methods document, and**
b) **The time to do so would not extend the PMN process beyond allotted 90-day deadline.**

However, we'd note that application of the New Chemical PBT policy referenced in previous TA is likely to be more stringent than the risk management standard included in the Senate PBT provision - "reduce exposure to the maximum extent practicable"

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Thursday, December 03, 2015 4:22 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Markey TSCA TA on PBTs

Quick follow up for you – would be great to get this by 5 pm or shortly thereafter. If EPA WAS told to score new chemicals using TSCA methods document criteria, a) would EPA have enough information on the new chemical to do so and b) how long would scoring take (days, weeks, months, etc?)

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey
<image001.png><image002.png><image003.png><image004.jpg>

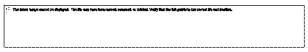
From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Thursday, December 03, 2015 2:04 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA on PBTs

Michal,

This responds to your TA requests on PBT determination and the follow on question about "maximum extent practicable".

1. Section 5 PBT language in S 697 requires EPA to know whether a new chemical scores high for P or B and high or moderate for the other in order to make it subject to the exposure reduction standard. Would this be a null set provision – how would EPA know that a chemical was P, B, or T, let alone the degree to which it had those properties, if it was new?

EPA currently reviews and categorizes new chemicals for persistence, bioaccumulation, and toxicity (PBT) characteristics under section 5 of TSCA in accordance with a policy statement published in 1999. A copy of the proposed and final policy is available on our website here. New chemicals are not currently scored "pursuant to" the 2012 Work Plan Chemicals Methods document. Because the language in 5(d)(4)(D) does not require a mandatory scoring of new chemicals for P or B pursuant to the Work Plan Chemicals Methods document, one possible outcome is that EPA never makes such a determination, and the specified risk management standard is never invoked.



Policy Statement on a New Chemicals Category for ...

On November 4, 1999, EPA issued its final policy statement (64 FR 60194) on a category for Persistent Bioaccumulative and Toxic new chemicals.

Read more...

2. Does EPA see a difference in a reduction exposure standard that directs EPA to choose restrictions for a PBT to "the extent practicable" as opposed to the "maximum extent practicable"? I assume an EPA administrator could decide that the extent practicable should mean the "maximum" extent, but would it be harder to defend a stringent restriction in court without the word "maximum" in statute?

As a purely linguistic matter, we do not see a significant difference between "to the extent practicable" and "to the maximum extent practicable" – the concept of "maximum" seems be implied in the first formulation. That having been said, arguments could certainly be raised that Congress' choice of the less explicit House formulation over the Senate formulation (in sections 5(d)(4)(D) and 6(d)(2)(B) of TSCA as modified by the Senate bill), indicates a choice to adopt a less demanding understanding of the extent to which EPA is required or authorized to reduce PBT exposure.

Please let me know if any additional questions. Thanks,

Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Thursday, December 03, 2015 4:44 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Cc: Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov>
Subject: Quick follow on on PBTs

Does EPA see a difference in a reduction exposure standard that directs EPA to choose restrictions for a PBT to "the extent practicable" as opposed to the "maximum extent practicable"? I assume an EPA administrator could decide that the extent practicable should mean the "maximum" extent, but would it be harder to defend a stringent restriction in court without the word "maximum" in statute?

Thanks
Michal

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

From: "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>
Date: November 24, 2015 at 10:11:33 PM EST
To: "Sven-Erik Kaiser (Kaiser.Sven-Erik@epamail.epa.gov)" <Kaiser.Sven-Erik@epamail.epa.gov>
Subject: PBT question
Sven

Question for you – section 5 PBT language in S 697 require EPA to know whether a new chemical scores high for P or B and high or moderate for the other in order to make it subject to the exposure reduction standard. Would this be a null set provision – how would EPA know that a chemical was P, B, or T, let alone the degree to which it had those properties, if it was new?

Thanks
Michal

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/15/2016 9:54:17 PM
To: Adrian_Deveny@merkley.senate.gov
Subject: Sen. Merkley TSCA TA on state waiver

Adrian,
This TA responds to the followup request on state waivers.

EPA believes that Option 2 is clearly broader in scope of inclusion than Option 1.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any questions. Thanks,

Sven

Sven-Erik Kaiser

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Office of Congressional and Intergovernmental Relations

1200 Pennsylvania Ave., NW (1305A)

Washington, DC 20460

202-566-2753

From: Deveny, Adrian (Merkley)
Sent: Friday, April 15, 2016 5:12 PM
To: 'Kaiser, Sven-Erik'
Subject: RE: Sen. Merkley TSCA TA on state waiver.

Thank you for this. Working from your language now, it looks it will not be possible to include "prioritization" or "is otherwise related". So, now my question is, which of these two options offers the most broad scope of inclusion for state rules to trigger eligibility for a waiver?

Option 1:

(B) the State or political subdivision of the State has promulgated a final administrative action or published a proposed administrative action, prior to the date on which the Administrator initiated a risk evaluation to be conducted on such chemical substance in accordance with section 6(b)(4)(D), that is for the assessment or management related to the effects of exposure to such chemical substance, and has submitted such final or proposed action to the Administrator.

Option 2:

(B) the State or political subdivision of the State has promulgated a final administrative action or published a proposed administrative action, prior to the date on which the Administrator initiated a risk evaluation to be conducted on such chemical substance in accordance with section 6(b)(4)(D), that is related to the effects of exposure to such chemical substance, and has submitted such final or proposed action to the Administrator.

"(2) REQUIRED EXEMPTIONS.—Upon application of a State or political subdivision of a State, the Administrator shall exempt from subsection (b) a statute or administrative action of a State or political subdivision of a State that relates to the effects of exposure to a chemical substance under the conditions of use if the Administrator determines that—

"

(B) the State or political subdivision of the State has promulgated a final administrative action or published a proposed administrative action, prior to the date on which the Administrator published the scope of the risk evaluation to be conducted on such chemical substance in accordance with section 6(b)(4)(D), that is for the prioritization, assessment, or management of such chemical substance or is otherwise related to the effects of exposure to such chemical substance, and has submitted such final or proposed action to the Administrator.

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Friday, April 15, 2016 2:00 PM

To: Deveny, Adrian (Merkley)
Subject: Sen. Merkley TSCA TA on state waiver.

Adrian,

This responds to the request on state preemption waivers.

Can EPA please take a look at the language in red below. The objective of this language is to a provide the opportunity for a state to obtain a waiver from pause pre-emption when essentially when the state has initiated its own rulemaking process to restrict a chemical prior to EPA. Some states do this with one rulemaking, and others do it with multiple rules in sequence, but the idea is that if a state has published a draft/proposed rule to prioritize a chemical prior to the start of the pause, then the final rule that does restrict the chemical can obtain an automatic waiver to be implemented during the pause.

First, does this language accomplish this objective?

No, because it doesn't clearly account for the fact that there are two different actions at issue: First, there is the action for which the state is seeking a preemption waiver; Second, there is the proposed or final *preliminary* action that predated EPA's scope publication, which is the basis for the state being entitled to the preemption waiver. What links the actions is that they relate to the same chemical substance, but there is no such linking language in the current draft. Also, the reference to a "draft" action should really be a reference to a "proposed" action. Here's the revised language, in context:

"(2) REQUIRED EXEMPTIONS.—Upon application of a State or political subdivision of a State, the Administrator shall exempt from subsection (b) a statute or administrative action of a State or political subdivision of a State that relates to the effects of exposure to a chemical substance under the conditions of use if the Administrator determines that—

…

> **(B) the State or political subdivision of the State has promulgated a final administrative action or published a proposed administrative action, prior to the date on which the Administrator published the scope of the risk evaluation to be conducted on such chemical substance in accordance with section 6(b)(4)(D), that is for the prioritization, assessment, or management of such chemical substance or is otherwise related to the effects of exposure to such chemical substance, and has submitted such final or proposed action to the Administrator.**

Second, if I strike the words "for prioritization, assessment, management or other action", would it achieve the same objective? (allowing precursor draft/final rules on priorizíation and assessment completed before EPA's scoping to provide a waiver from the puase to the final state rule to restrict a chemical)

Deleting the words would make the passage less likely to function in the manner you intend. The phrase "prioritization, assessment, or management" helps to illustrate what you mean by an action that is "related to the effects of exposure." Even though the illustrative list is just a subset of what is already included under the heading of "related to," an illustrative list helps to guard against courts

later construing "related to" more narrowly than you intend (e.g., deciding that prioritization can't be related to the effects of exposure because the state hasn't yet definitively figured out what those effects are at the stage of prioritization).

Section 18(f)(2) Required Exemptions.—

"(2) REQUIRED EXEMPTIONS.—Upon application of a State or political subdivision of a State, the Administrator shall exempt from subsection (b) a statute or administrative action of a State or political subdivision of a State that relates to the effects of exposure to a chemical substance under the conditions of use if the Administrator determines that—

"(A) (i) compliance with the proposed requirement of the State or political subdivision of the State would not unduly burden interstate commerce in the manufacture, processing, distribution in commerce, or use of a chemical substance;

"(ii) compliance with the proposed requirement of the State or political subdivision of the State would not cause a violation of any applicable Federal law, rule, or order; and

"(iii)the State or political subdivision of the State has a concern about the chemical substance or use of the chemical substance based in peer-reviewed science; or

(B) the State or political subdivision of the State has promulgated a final administrative action or published a proposed administrative action on a chemical substance for prioritization, assessment, management, or other action related to the effects of exposure to the chemical substance prior to the date on which the Administrator published the scope of the risk evaluation to be conducted on the chemical substance in accordance with section 6(b)(4)(D), and has submitted such draft or final action to the Administrator."

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any questions. Thanks,

Sven

Sven-Erik Kaiser

U.S. EPA

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1200 Pennsylvania Ave., NW (1305A)

Washington, DC 20460

202-566-2753

From: "Deveny, Adrian (Merkley)" <Adrian_Deveny@merkley.senate.gov>
Date: April 14, 2016 at 9:44:32 PM EDT
To: "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov>
Subject: TA on waiver

Sven

Can EPA please take a look at the language in red below. The objective of this language is to a provide the opportunity for a state to obtain a waiver from pause pre-emption when essentially when the state has initiated its own rulemaking process to restrict a chemical prior to EPA. Some states do this with one rulemaking, and others do it with multiple rules in sequence, but the idea is that if a state has published a draft/proposed rule to prioritize a chemical prior to the start of the pause, then the final rule that does restrict the chemical can obtain an automatic waiver to be implemented during the pause.

First, does this language accomplish this objective?

Second, if I strike the words "for prioritization, assessment, management or other action", would it achieve the same objective? (allowing precursor draft/final rules on priorizíation and assessment completed before EPA's scoping to provide a waiver from the puase to the final state rule to restrict a chemical)

Section 18(f)(2) Required Exemptions.—

"(2) REQUIRED EXEMPTIONS.—Upon application of a State or political subdivision of a State, the Administrator shall exempt from subsection (b) a statute or administrative action of a State or political subdivision of a State that relates to the effects of exposure to a chemical substance under the conditions of use if the Administrator determines that—

"(A) (i) compliance with the proposed requirement of the State or political subdivision of the State would not unduly burden interstate commerce in the manufacture, processing, distribution in commerce, or use of a chemical substance;

"(ii) compliance with the proposed requirement of the State or political subdivision of the State would not cause a violation of any applicable Federal law, rule, or order; and

"(iii)the State or political subdivision of the State has a concern about the chemical substance or use of the chemical substance based in peer-reviewed science; or

(B) the State or political subdivision of the State has promulgated a final administrative action or published a proposed administrative action on a chemical substance for prioritization, assessment, management, or other action related to the effects of exposure to the chemical substance prior to the date on which the Administrator published the scope of the risk evaluation to be conducted on the chemical substance in accordance with section 6(b)(4)(D), and has submitted such draft or final action to the Administrator."

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/8/2016 11:23:49 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Re: Sen. Markey TSCA TA Section 19

Great- have a good night- I'll keep an eye on things in case anything comes up. Thanks,
Sven

On Apr 8, 2016, at 7:19 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Thanks -- I think my problem was the x-ref issue you noted.

Michal Ilana Freedhoff, Ph.D.
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255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey
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From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Friday, April 08, 2016 4:00 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA Section 19

Michal,
This TA responds to the request on section 19. We don't see any inconsistency between TA we sent to you and TA we sent to Dmitri. In any event, attached is our TA on the revised section you sent.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
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1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>
Date: April 7, 2016 at 8:43:34 PM EDT
To: "Sven-Erik Kaiser (Kaiser.Sven-Erik@epamail.epa.gov)" <Kaiser.Sven-Erik@epamail.epa.gov>
Cc: "Karakitsos, Dimitri (EPW)" <Dimitri_Karakitsos@epw.senate.gov>, "Deveny, Adrian (Merkley)"

<Adrian_Deveny@merkley.senate.gov>, "Black, Jonathan (Tom Udall)"
<Jonathan_Black@tomudall.senate.gov>
Subject: Section 19

Sven

I'm having trouble reconciling the TA you sent Dimitri (pasted below) with the TA you sent me when I asked for the rest of the Senate-offer conforming changes to 19 (attached). You sent me some changes to cross-refs in the same section of text that you helped Dimitri with, and the cross-references don't seem to match up or maybe I am misunderstanding. Could you take a look at this whole section, with particular attention paid to the yellow highlighted text?

Thanks
Michal

The TA you sent Dimitri:
That said, option 1 is largely harmless if properly edited. To be consistent with the overall structure of the Senate bill, it should read: "section 4(a), 6(d) (including review of **the** associated determination under section 6(c)(1)(B)), or 6(**h**), or an order under section 6(c)(1)(A)." The definite article is to maintain consistency with 6(f)(2), which refers to "the associated safety assessment and safety determination." Referring to "an associated determination" could give rise to arguments that other safety determinations (i.e., other than the one that gave rise to the risk management rule) are sufficiently associated with the rule that they should be reviewed as part of the risk management rule.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/13/2016 9:17:31 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Re: PBT question - why wouldn't something like this work? House did this

Great - please call Ex. 6 - Personal Privacy code Ex. 6 - Personal Privacy

On Apr 13, 2016, at 5:16 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Sure. I'm at my desk or I can call in.

Michal Ilana Freedhoff, Ph.D.
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Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

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<image001.png><image002.png><image003.png><image004.jpg>

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Wednesday, April 13, 2016 5:12 PM
To: Freedhoff, Michal (Markey)
Subject: Re: PBT question - why wouldn't something like this work? House did this

Michal,
Do you have a minute for a call on this? We're meeting now. Thanks,
Sven

On Apr 13, 2016, at 4:20 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

(a) SCOPE OF REGULATION. If the Administrator determines in accordance with subsection (b)(4)(A) that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents an unreasonable risk of injury to health or the environment, OR DESIGNATES THE SUBSTANCE UNDER THE PBT PARA the Administrator shall by rule, and subject to section 18 and in accordance with subsection (c)(2), apply one or more of the following requirements to such substance or mixture to the extent necessary so that the chemical substance does not present such a risk under the conditions of use.:

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255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey
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Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/3/2016 12:46:52 PM
To: Cohen, Jacqueline [jackie.cohen@mail.house.gov]
Subject: HEC Min TSCA TA request on nomenclature

Jacqueline,
This TA responds to the request on nomenclature.

We would need to see the actual savings clause to respond definitively, but we are concerned this approach will not resolve the fundamental issue underlying much of section 8(b)(3): what chemical substances are currently on the inventory? Much of this section addresses areas of current disagreement as to the scope of existing inventory listings, and it apparently is intended to resolve those issues. It sounds like the suggested approach would simply beg the question of what chemical substances are on the inventory (and what the purpose of section 8(b)(3) is, if not to provide direction in that regard).

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser

U.S. EPA

Office of Congressional and Intergovernmental Relations

1200 Pennsylvania Ave., NW (1305A)

Washington, DC 20460

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On Mar 31, 2016, at 4:12 PM, Cohen, Jacqueline <jackie.cohen@mail.house.gov> wrote:

Sven,

I am working on a savings clause that could be added to the nomenclature language in section 8 of the Senate bill to make clear that it only applies to chemical substances on the inventory as of the date of enactment. In other words, a chemical that would be considered new and subject to Section 5 if not for the language will continue to be considered new and subject to section 5. Do I need to distinguish between the various paragraphs in the nomenclature language, or can I treat them all alike for purposes of the savings clause?

Jacqueline G. Cohen
Senior Counsel
Committee on Energy and Commerce, Democratic Staff
U.S. House of Representatives
jacqueline.cohen@mail.house.gov
202-225-4407

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/21/2016 11:02:03 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TA Request on Section 6 (4-20) Part 2 - REs

Michal – thanks for the information. Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
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Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Thursday, April 21, 2016 7:00 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Re: Sen. Markey TSCA TA Request on Section 6 (4-20) Part 2

On industry requested RES - we want this demoninator. Makes it 2:1 EPA:industry.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

From: Kaiser, Sven-Erik
Sent: Thursday, April 21, 2016 6:28 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA Request on Section 6 (4-20) Part 2

Michal,
The attached TA responds to the request on section 6 (4-20). This is additional TA on section 6, on top of the TA we sent earlier today (Part 1). The TA is in 3 colors: green (the TA you already got, unchanged), yellow (new TA on the changes that we had not picked up on in our earlier run through), and blue (repeated TA from our comments on the previous version, so it's all in one place).

The most significant new issue (in yellow, p 25) is the observation that TSCA section 6(d)(2) – authorizing EPA to make section 6 proposals enforceable in certain circumstances – seems to have been stricken completely.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments. Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
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1200 Pennsylvania Ave., NW (1305A)
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202-566-2753

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/12/2016 2:24:50 AM
To: Michal_Freedhoff@markey.senate.gov
Subject: Sen. Markey TSCA TA on section 5 "may present"
Attachments: Paragraph 6(d)(2) TA.doc; ATT00001.htm

Michal, this responds to your YA request in section 5 determinations. Please see the attached TA along with the comments below.

Option #1 … This won't work well. If EPA has a basis to say that a chemical substance "may present" an UR, there is no direction about whether to make that finding or whether to just give the chemical a pass, which is an alternative option. The intention is presumably that EPA can make the "may commence" finding only if EPA has no basis to make the "may present" finding, but the language does not say that. This option also presents some of the issues identified for option 2.

Option 2 seems to provide clearer direction but raises some issues, identified, with suggested possible fixes, in the attachment.

Sven

This is for after you're done with the TA requests that are pending from me and Jonathan. I'm returning to the development/exploration of options for compromise in the event that we need them based on input we have received about House concerns. I'm trying to understand the drawbacks of what may be proposed rather than waiting to react real-time absent your input, or, in the event I can figure out a workable option with your input, have it ready. When I last sent you some options for Section 5 that did not include a requirement that EPA make a determination that a new chemical was safe but requiring it to determine that manufacture could commence, you noted that the determination that manufacture could commence had no legal standard attached to it, and also noted that our standard for what is 'unsafe' had changed. What follows below are 2 efforts to address the concern and use the TA you provided. If they are totally unworkable, I'd like to know that and know why.

Thanks
Michal

OPTION 1

(2) DETERMINATIONS.—
(A) the Administrator shall determine, without consideration of costs or other non-risk factors, that the chemical substance or significant new use may present an unreasonable risk of injury to health or the environment from potential exposure to a chemical substance under the conditions of use identified in the notice to the general population or to a potentially exposed or susceptible population identified as relevant by the Administrator and take applicable action under paragraph (3), or determine that manufacture of the chemical substance, or manufacture and processing of the chemical substance for the significant new use may commence (notwithstanding any remaining portion of the applicable period for review under subsection (b)(1)).
(B) If the Administrator determinesthat information available to the Administrator is insufficient to permit a reasoned evaluation of the health and environmental effects of the chemical substance or significant new use in order to make a determination under subparagraph (A), the Administrator—

(i) shall provide an opportunity for the submitter of the notice to submit the information, and may extend the review period for a reasonable amount of time by agreement with the submitter to allow the development and submission of the information;
(ii) may promulgate a rule, enter into a consent agreement, or issue an order under section 4 to require the development of the information; and
(iii) shall, on receipt of information the Administrator finds sufficient to support a determination under subparagraph (A), promptly make the determination, and take action under paragraph (3) as applicable.

OPTION 2

(2) DETERMINATIONS.—
(A) the Administrator shall determine, without consideration of costs or other non-risk factors, whether the chemical substance or significant new use may present an unreasonable risk of injury to health or the environment from potential exposure to a chemical substance under the conditions of use identified in the notice to the general population or to a potentially exposed or susceptible population identified as relevant by the Administrator, and take applicable action under paragraph (3).
(B) If the Administrator determines that information available to the Administrator is insufficient to permit a reasoned evaluation of the health and environmental effects of the chemical substance or significant new use in order to make a determination under subparagraph (A), the Administrator—

(i) shall provide an opportunity for the submitter of the notice to submit the information, and may extend the review period for a reasonable amount of time by agreement with the submitter to allow the development and submission of the information;
(ii) may promulgate a rule, enter into a consent agreement, or issue an order under section 4 to require the development of the information; and
(iii) shall, on receipt of information the Administrator finds sufficient to support a determination under subparagraph (A), promptly make the determination, and take action under paragraph (3) as applicable.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

(2) DETERMINATIONS.—

(A) the Administrator shall determine, without consideration of costs or other non-risk factors, whether the chemical substance or significant new use may present an unreasonable risk of injury to health or the environment from potential exposure to a chemical substance under the conditions of use identified in the notice to the general population or to a potentially exposed or susceptible population identified as relevant by the Administrator, and take applicable action under paragraph (3).

(B) If the Administrator determines that information available to the Administrator is insufficient to permit a reasoned evaluation of the health and environmental effects of the chemical substance or significant new use in order to make a determination under subparagraph (A), the Administrator—

(i) shall provide an opportunity for the submitter of the notice to submit the information, and may extend the review period for a reasonable amount of time by agreement with the submitter to allow the development and submission of the information;

(ii) may promulgate a rule, enter into a consent agreement, or issue an order under section 4 to require the development of the information; and

(iii) shall, on receipt of information the Administrator finds sufficient to support a determination under subparagraph (A), promptly make the determination, and take action under paragraph (3) as applicable.

Commented [BG1]: Suggest deleting "identified in the notice" because EPA routinely issues section 5 orders, often with follow-up SNURs, to address potential risks from foreseeable uses not identified in section 5 notices.

Commented [BG2]: EPA REVIEWERS: NOTE THAT THIS COMMENT IDENTIFIES AN ADDITIONAL DRAFTING POINT WE DID NOT DISCUSS We are assuming that the "paragraph (3)" is paragraph (3) of the current Senate offer. If so, the intro text of (3) will need to be modified, because the obligation for EPA to issue an order or consent agreement under the Senate offer is triggered by "a determination" under (2)(A). Since the determination could go either way under this new paragraph (2)(A), presumably (3) should be revised so that an order or consent decree is triggered only by a determination that the chemical may present unreasonable risk.

Commented [BG3]: We suggest deleting "permit a reasoned. . . in order to take". The inference in your text that this level of information is needed to make a "may present" determination would significantly raise the bar for such a determination as compared with current TSCA. Indeed, under TSCA section 4 and 5(e), the absence of information sufficient to make a reasoned evaluation of health effects is a *prerequisite* to making a may present finding. As revised by our suggested deletion, this provision would still indicate that there might be times when EPA would lack sufficient information to make a "may present" determination, without suggesting that the amount of information that would be needed is particularly high.

Commented [BG4]: Suggest adding, after "the Administrator", "shall take applicable action under paragraph (3) and". Paragraph (3) of the Senate offer requires EPA to issue an order or consent decree if it "makes a determination under paragraphs (2)(A) or (2)(C)". We are assuming that a conforming change would be made to change "(2)(C)" to "(2)(B)", since the new (2)(B) seems to replace (2)(C) from the offer. If so, then the wording of (2)(B) should parallel (2)(A) and reflect that EPA will be taking action under (2)(C) upon finding that it has insufficient information to make a determination. If (2)(B) and (3) are not linked, then manufacture of a new chemical could commence while information is being generated on the chemical and without an EPA determination that it is not likely to present and unreasonable risk.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/17/2016 6:25:50 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TA Request on Section 6 cost considerations
Attachments: Updated Table on Cost Considerations.docx

Michal – please see the requested TA in the updated chart. The new options are labeled Senate offer and Supplemented Senate Offer. Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Monday, March 07, 2016 2:22 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: TA request - Section 6 cost considerations

In the same spirit and on the same timeframe as the others I've sent today, can this redline to what was sent to the House last week AND the version of the language that was sent to the House last week be ranked/added to the table from the 01/05/16 TA?

Thanks
Michal

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

1) Can you rank these in order of added analytic burden to EPA (ie analysis above what is already required under administrative law, RIA, what EPA would expect to do as part of any rulemaking analysis, etc), and describe briefly the basis for the ranking?

2) Can you rank these in order of added litigation risk that the formulations may present, and describe (briefly) the basis for the ranking?

Cost Considerations in a Rule

- **"S 697"**

"(4) ANALYSIS FOR RULEMAKING.—

"(A) CONSIDERATIONS.—In deciding which restrictions to impose under paragraph (3) as part of developing a rule under paragraph (1), the Administrator shall take into consideration, to the extent practicable based on reasonably available information, the quantifiable and nonquantifiable costs and benefits of the proposed regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator.

"(B) ALTERNATIVES.—As part of the analysis, the Administrator shall review any 1 or more technically and economically feasible alternatives to the chemical substance that the Administrator determines are relevant to the rulemaking.

"(C) PUBLIC AVAILABILITY.—In proposing a rule under paragraph (1), the Administrator shall make publicly available any analysis conducted under this paragraph.

"(D) STATEMENT REQUIRED.—In making final a rule under paragraph (1), the Administrator shall include a statement describing how the analysis considered under subparagraph (A) was taken into account.

- **"MERGED HOUSE/SENATE PROPOSAL"**

d) PROMULGATION OF SUBSECTION (b) RULES.

(1) **REQUIREMENTS FOR RULE.**—In promulgating any rule under subsection (b) with respect to a chemical substance or mixture, the Administrator shall factor in the following considerations, and publish a statement describing how they were factored into the rule—

(A) the effects of ~~such~~ **the chemical** substance or mixture on health and the magnitude of the exposure of human beings to **the chemical** ~~such~~ substance or mixture;

(B) the effects of ~~such~~ **the chemical** substance or mixture on the environment and the magnitude of the exposure of the environment to such substance or mixture~~,~~**;**

(C) the benefits of ~~such~~ **the chemical** substance or mixture for various uses; and ~~the availability of substitutes for such uses, and~~

(D)) the reasonably ascertainable economic consequences of the rule, after consideration of

(i) ~~after~~ the **likely** effect ~~on~~ **of the rule on** the national economy, small business, technological innovation, the environment, and public health**;**~~.~~

(ii) the quantifiable and nonquantifiable costs and benefits of the proposed regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator. ;

(E) any 1 or more technically and economically feasible alternatives to the chemical substance that the Administrator determines are relevant to the rulemaking. ;

❖ **"SENATE OFFER"**

(2) REQUIREMENTS FOR RULE.—

(A) In promulgating a rule under subsection (a) with respect to a chemical substance or mixture, the Administrator shall consider and publish a statement based on reasonably available information with respect to—

(i) the effects of the chemical substance or mixture on health and the magnitude of the exposure of human beings to the chemical substance or mixture,;

(ii) the effects of the chemical substance or mixture on the environment and the magnitude of the exposure of the environment to such substance or mixture,;

(iii) the benefits of the chemical substance or mixture for various uses; and

(iv) the reasonably ascertainable economic consequences of the rule, after consideration of:

(v) the likely effect of the rule on the national economy, small business, technological innovation, the environment, and public health; and

(vi) The quantifiable and non-quantifiable costs and benefits of the proposed regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator;

(B) In deciding which requirements to impose as part of developing the rule under subsection (a), the Administrator shall take into consideration, to the extent practicable, the considerations required under subparagraph (A).

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

❖ **"SUPPLEMENTED SENATE OFFER"**

(2) REQUIREMENTS FOR RULE.—

(A) In promulgating a rule under subsection (a) with respect to a chemical substance or mixture, the Administrator shall consider and publish a statement based on reasonably available information with respect to—

(i) the effects of the chemical substance or mixture on health and the magnitude of the exposure of human beings to the chemical substance or mixture,;

(ii) the effects of the chemical substance or mixture on the environment and the magnitude of the exposure of the environment to such substance or mixture,;

(iii) the benefits of the chemical substance or mixture for various uses; and

(iv) the reasonably ascertainable economic consequences of the rule, after consideration of:

(v) the likely effect of the rule on the national economy, small business, technological innovation, the environment, and public health; and

(vi) The quantifiable and non-quantifiable costs and benefits of the proposed regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator;

(B) In deciding which requirements to impose as part of developing the rule under subsection (a), the Administrator shall take into consideration, to the extent practicable, the considerations required under subparagraph (A) **and shall consider whether the proposed regulatory action and the 1 or more primary alternative regulatory actions considered by the Administrator under subparagraph (A)(vi) are cost-effective.**

❖ **"H.R. 2576 AS MODIFIED USING EPA TA"**

(B) impose requirements under the rule that the Administrator determines, to the extent practicable based on the information published under subparagraph (A), are cost-effective, except where the Administrator determines that additional or different requirements described in subsection (a) are necessary to ensure that the chemical substance no longer presents or will present an unreasonable risk, including an identified unreasonable risk to a potentially exposed population.

❖ **"H.R. 2576"**

(B) impose requirements under the rule that the Administrator determines, consistent with the information published under subparagraph (A), are cost-effective, except where the Administrator determines that additional or different requirements described in subsection (a) are necessary to protect against the identified risks.

	Burden relative to baseline	**Litigation Risk**
S. 697	**Lowest Analytical Burden Relative to Baseline** Roughly tracks E.O. 12866 requirements, but applies irrespective of whether action deemed "significant" under the E.O. Analytical burden limited to what is "practicable" and data inputs limited to what is "reasonably available" Statement describing how analysis was taken into account is already a baseline requirement of administrative law.	**Lowest Litigation Risk** Litigation opportunities to challenge rule roughly track what would already be available under APA under the substantial evidence standard, Scope of litigation would roughly track typical APA litigation, except that failure to include mandatory considerations in the overall discussion of why the rule is warranted would be a basis Most of these considerations would likely be raised by stakeholders in public comment anyway, which would establish an obligation for EPA to consider the issues, even if they were not statutorily specified.
Senate Offer	**Second Lowest Analytical Burden Relative to Baseline** The Senate Offer is identical to the Merged House/Senate proposal, except that the requirement for consideration of chemical alternatives has been deleted. This somewhat reduces analytical burden.	**Second Lowest Litigation Risk** The Senate Offer is identical to the Merged House/Senate proposal, except that the requirement for consideration of chemical alternatives has been deleted. This somewhat reduces the range of issues that might be the basis of litigation.

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	Burden relative to baseline	**Litigation Risk**
Merged House/Senate Proposal	**Third Lowest Analytical Burden Relative to Baseline** Roughly tracks E.O. 12866 requirements, but applies irrespective of whether action deemed "significant" under the E.O. Analytical burden limited to what is "practicable" and data inputs limited to what is "reasonably available" Requirement to "factor" considerations into a decisions and publish explanatory statement is already a baseline requirement of administrative law. No increase in burden from requirement to "consider and publish a statement"	**Third Lowest Litigation Risk** Litigation opportunities to challenge rule roughly track what would already be available under APA under the substantial evidence standard, Scope of litigation would roughly track typical APA litigation, except that failure to include mandatory considerations in the overall discussion of why the rule is warranted would be a basis Most of these considerations would likely be raised by stakeholders in public comment anyway, which would establish an obligation for EPA to consider the issues, even if they were not statutorily specified. Relative to H.R. 2576, list of mandatory factors is more prescriptive, somewhat increasing litigation opportunities to claim EPA failed to consider one of the points.

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

	Burden relative to baseline	**Litigation Risk**
Supplemented Senate Offer	**Fourth Lowest Analytical Burden Relative to Baseline** The Senate Offer is identical to the Merged House/Senate proposal, except that the requirement for consideration of chemical alternatives has been deleted and a requirement to consider cost-effectiveness has been added. Overall, there is probably greater analytical burden in demonstrating that one considered cost-effectiveness than in demonstrating that one considered 1 or more chemical alternatives, so this is a slight net increase in burden.	**Fourth Lowest Litigation Risk** The Senate Offer is identical to the Merged House/Senate proposal, except that the requirement for consideration of chemical alternatives has been deleted and a requirement to consider cost-effectiveness has been added; Overall, there is probably greater litigation risk in demonstrating that one considered cost-effectiveness than in demonstrating that one considered 1 or more chemical alternatives, so this is a slight net increase in litigation risk.

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

	Burden relative to baseline	**Litigation Risk**
H.R. 2576 as modified by EPA TA	**Fifth Lowest Analytical Burden Relative to Baseline** EPA must either justify substantive economic conclusion that regulation is "cost-effective" or that a non-cost-effective alternative was "necessary." Introduces a requirement to determine that the selected option is cost-effective, or, if EPA selects a non-cost-effective option, to determine that there are no protective cost-effective options; but these analytic burdens are bounded by what is practicable based on the information already required to be considered in the rulemaking. Failure to meet the safety standard is clearly a basis to deem an alternative unacceptable. Arguably also implicitly limited by the "reasonably ascertainable" caveat in paragraph (A), regarding analysis of economic consequences.	**Fifth Lowest Litigation Risk** Establishes a new legal duty, above and beyond baseline obligations to justify the rule, to either make a "cost-effectiveness" determination or a "necessity" determination. The determination could be a basis for additional litigation claims. There is some uncertainty about how many cost-effective alternatives EPA must screen and find to be unsuitable in order to conclude that a non-cost-effective alternative is necessary, but this is moderated by the "practicable" language.

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

	Burden relative to baseline	Litigation Risk
H.R. 2576	**Highest Introduced Burden Relative to Baseline** EPA must either justify substantive economic conclusion that regulation is "cost-effective" or that a non-cost-effective alternative was "necessary." Introduces the same analytic objectives as paragraph (B) as modified, but the analysis is less clearly bounded by the information already required to be considered in the rulemaking. Failure to meet the safety standard is very likely a basis to deem an alternative unacceptable. Arguably implicitly limited by the "reasonably ascertainable" caveat in paragraph (A), regarding analysis of economic consequences.	**Highest Litigation Risk** Establishes a new legal duty, above and beyond baseline obligations to justify the rule, to either make a "cost-effectiveness" determination or a "necessity" determination. The determination could be a basis for additional litigation claims. There is significant uncertainty about how many cost-effective alternatives EPA must screen and find to be unsuitable in order to conclude that a non-cost-effective alternative is necessary.

Appointment

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 12/8/2016 5:02:49 PM
To: Poirier, Bettina (EPW [Bettina_Poirier@epw.senate.gov]; 'Albritton, Jason (EPW)' [Jason_Albritton@epw.senate.gov]; Fox, Thomas (EPW [Thomas_Fox@epw.senate.gov]

Subject: EPA Briefing on TSCA New Chemicals Review Program
Location: 406 Dirksen

Start: 12/12/2016 7:00:00 PM
End: 12/12/2016 8:00:00 PM
Show Time As: Tentative

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 11/17/2016 1:24:20 PM
To: Michal_Freedhoff@markey.senate.gov
Subject: Notification: EPA Announces Public Meeting on TSCA New Chemicals Review - December 14

Michal,
Heads up that EPA is holding a meeting to update the public on changes to the TSCA New Chemicals Review Program on Weds, Dec 14. EPA will describe the review process for new chemicals under the amended statute, as well as discuss issues, challenges, and opportunities that the agency has identified in the first few months of implementation. Interested parties will have the opportunity to provide input on their experiences with the New Chemicals Review Program, including submittal of pre-manufacture notices (PMNs), microbial commercial activities notices (MCANs), and significant new use notices (SNUNs), under section 5 of the law. Information obtained during this meeting and from submitted written comments will be considered as EPA implements the new requirements and increases efficiency in its review process under TSCA.

Register for the meeting in advance: We ask that you please register for this meeting by December 13, 2016.

Date and Time: Wednesday, December 14, 2016, from 9:00 a.m. to 12:00 p.m.

Location: The Ronald Reagan Building and International Trade Center, Polaris Room, 1300 Pennsylvania Avenue Northwest, Washington, DC 20004

Docket number to submit written comments: EPA-HQ-OPPT-2016-0658 (Docket will be open prior to and remain open after the meeting.)

We're continuing work on your TSCA implementation requests (as well as the asbestos/PCB bill TA). Please let me know if you would like a briefing on new chemicals program prior to or in connection with the public meeting. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/3/2016 5:27:16 AM
To: Michal_Freedhoff@markey.senate.gov
Subject: Fwd: Follow up on Sen. Market TSCA TA request- Senate section 4/5

Michal, TA on the section 4/5 references. Thanks,
Sven

Quick follow up - what if the section 4 reference in the language was retained but the section 5 consent agreement reference was removed?

Retention of the section 4 reference seems unnecessary for the reasons discussed in prior TA. If the PMN was the sole reason for the testing requirement, EPA issued a consent agreement or order to the PMN submitter, and the PMN was then withdrawn, EPA would have no rational basis to retain the testing requirement and no rational basis to refuse a request to withdraw the requirement.

However, retention of the section 4 reference, with respect to orders and consent agreements, seems unlikely to raise implementation problems. Note that the issue might be more complicated with a test rule directed at a broader category of manufacturers or processors, since it is possible that some other reason for a test rule might have emerged, other than the initial PMN, which might continue to warrant testing to be performed by other parties.

If a choice is made to retain the section 4 reference, the drafting needs to be tightened up, regarding the relationship between the section 4 CA/order to be nullified and the PMN that has been withdrawn. We believe the following reflects your objectives:

- "A consent agreement or order issued pursuant to Section 4, solely to develop information that the Administrator found to be necessary in order to make a determination on the notice under subsection (d), shall cease to have legal effect on the date the notice is withdrawn."

From: "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>

Date: March 1, 2016 at 7:15:44 PM EST
To: "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov>
Subject: Re: Sen. Market TSCA TA request- Senate section 5

Quick follow up - what if the section 4 reference in the language was retained but the section 5 consent agreement reference was removed?

Thanks

M

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

From: Kaiser, Sven-Erik

Sent: Tuesday, March 1, 2016 7:08 PM

To: Freedhoff, Michal (Markey)

Subject: Sen. Market TSCA TA request- Senate section 5

Michal - this responds to your request on sect 5. Please let me know if any questions. Thanks,

Sven

The proviso under discussion is unnecessary. A section 5 consent agreement generally does not impose testing requirements. See the sample at: http://www.epa.gov/sites/production/files/2016-01/documents/co_all_purpose_preamble_and_consent_order_combined_1-5-2016.pdf at page 6. The order imposes restrictions on the manufacturing, processing, distribution in commerce, use, and disposal of a chemical substance, which continue until such time as EPA receives particular test data. If manufacture never commences in the first place, then there would generally be no testing obligations under the consent agreement. In the event that testing obligations *were* directly incorporated into a section 5 consent agreement, the parties to the agreement would not need statutory authorization to negotiate mutually agreeable terms for the termination of such testing obligations (in the event that manufacture never commences), as part of the original development of the consent agreement.The proviso under discussion could also be harmful. It would entitle a prospective manufacturer to renegotiate or litigate the terms of an existing consent agreement at any point prior to the commencement of manufacture, simply by withdrawing the PMN that was the basis for the consent agreement and then resubmitting the PMN for a fresh 90-day review. Consent agreements would not provide the same assurance of repose for EPA, at least until such time as EPA had made the key terms of the consent agreement generally binding by incorporating them into a Significant New Use Rule.

From: "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>

Date: February 29, 2016 at 2:24:31 PM ES

To: "Sven-Erik Kaiser (Kaiser.Sven-Erik@epamail.epa.gov)" <Kaiser.Sven-Erik@epamail.epa.gov>

Subject: TA request- Senate section 5

Sven

Last week I asked you what would happen to a test order/consent agreement under section 5 in the event that a PMN was withdrawn, and your response was that there would be no reason for it to continue in effect and EPA had authority to withdraw it.

The same question has now arisen about an instance in which EPA has entered into a section 5 consent agreement with the PMN submitter and the submitter then withdraws the PMN before submitting a NOC. The question is whether to add a "cease in effect" provision to capture both the section 4 and the section 5 consent agreement scenarios. Is there any circumstance EPA can think of that would make it wish to keep a section 5 consent agreement in effect on a PMN submitter even after the PMN is withdrawn?

Pasting the relevant language below in case it is helpful.

Michal

(e) Notice of Commencement.—

(1) IN GENERAL.—Not later than 30 days after the date on which a manufacturer that has submitted a notice under subsection (b) commences nonexempt commercial manufacture of a chemical substance, the manufacturer shall submit to the Administrator a notice of commencement that identifies—

(A) the name of the manufacturer; and

(B) the initial date of nonexempt commercial manufacture.

(2) WITHDRAWAL.—A manufacturer or processor that has submitted a notice under subsection (b), but that has not commenced nonexempt commercial manufacture or processing of the chemical substance, may withdraw the notice. A consent agreement or order issued pursuant to Section 4 [and subsection (d)(3)(A)(i)(I)] shall cease to have legal effect on the date the notice is withdrawn.

Michal Ilana Freedhoff, Ph.D.

Director of Oversight & Investigations

Office of Senator Edward J. Markey

255 Dirksen Senate Office Building

Washington, DC 20510

202-224-2742

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/15/2016 9:44:51 PM
To: Michal_Freedhoff@markey.senate.gov
Subject: Sen. Markey TSCA TA Request on House Min section 5
Attachments: EPA TA on Section 5 qs.docx; ATT00001.htm

Michal- TA responding to the request on section 5 and low hazard, including attachment.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Thursday, April 14, 2016 7:09 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Fw: section 5

I am not sure how much I need this evaluated but big picture thoughts welcome.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

TA Requests Regarding Section 5

I am not sure how much I need this evaluated but big picture thoughts welcome.

EPA has not had an opportunity to do a complete review of this section, but we have some general observations and we note a few apparent typographical errors in key locations of the text:

- Page 1, Line 13: The amendatory instructions to strike "significant new use" are broken. They disrupt the basic obligation for manufacturers and processors to submit SNUNs before embarking on significant new uses.
- Page 2, Lines 11: The reference to paragraph (3)(B) is apparently mistaken. It appears intended to reference the scenario where EPA concludes it needs more information, but it actually references the low hazard provision. It would not make sense as currently drafted.
- Page 2, line 12: As in the Senate draft, an order under (e)(1)(A) is a pre-requisite for manufacturing to proceed in the interim, in the event that EPA determines that additional information is necessary to act on the notice. Yet the House draft does not amend the text of 5(e) from current TSCA. Retaining current TSCA 5(e) is a serious structural problem with the drafting of this bill. For example:
    - EPA cannot issue a 5(e) order under current TSCA 5(e) unless it can make a "may present an unreasonable risk" finding or a substantial exposure/release finding. But now, EPA's inability to justify interim risk management under 5(e) would lead to a complete interim ban. This seems paradoxical.
    - If EPA were in a position to justify a 5(e) order by making a "may present" finding, that would suggest it shouldn't issue a 5(e) order at all, but rather a 5(f) order. This also seems paradoxical.
    - The bill references provisions of Senate 5(e) that don't exist under existing TSCA (e.g,. page 3 line 24)
    - It make little sense to retain the elaborate judicial proceedings provisions under 5(e) (deleted from 5(f)), given that the default in the absence of a 5(e) order is a complete ban on the manufacture of the chemical.
- Page 3, lines 5-9: The low hazard language under (3)(B) introduces significant conceptual confusion into the framework of Section 5. Any substantive judgment about the hazards of a chemical should would ordinarily be presumed to be encompassed by the broader risk inquiry under (A). Is the "low hazard" evaluation actually deemed to be an independent inquiry from whether the substance may present an unreasonable risk? If yes, is it still part of the notification under (g)? Is a low hazard determination an alternative to or supplement to determining that a substance does or does not meet the may present standard under (A)?

Under this language, epa is basically told to designate a chemical that it does not make a "may present" finding as the term that appears to be intended to be used to describe what is a "low priority" chemical substance in the Senate lexicon.

In EPA's opinion, would this create a second standard for what "low priority" is, where the information available to EPA about a substance that was so designated through section 5 review could be far less extensive than that for a substance so designated through the section 6 review?

Our concern is that some might construe paragraph (3) as requiring EPA to designate a substance as a "low hazard" (which actually means "no hazard," under Section 6) in every case where it decides that the "may present" finding is unjustified. That would be the second of the two possible interpretations we see here.

- Interpretation I: EPA is supposed to either: (A) Determine that a chemical substance is a may present or not a "may present"; (B) Determine that the chemical substance is "low hazard"; or (C) Determine that additional information is necessary.

- Interpretation II: EPA is supposed to either: (A) Determine that a chemical substance is a may present; (B) Determine that the chemical substance is "low hazard"; or (C) Determine that additional information is necessary. .

As we understand the use of this term in Section 6, "low hazard" actually means no hazard. EPA does not agree that it would be appropriate to conclude that a chemical substance poses no hazard, simply because a "may present an unreasonable risk" determination was not justified. Conversely, EPA does not agree that it must designate a chemical substance as a "may present" unless it can justify that the chemical substance poses no hazard whatsoever.

The specific issue of information availability does not seem particularly worrisome, because under either interpretation, EPA could gather more information necessary.

Would TBB have been designated a "low priority" substance under this language when it first came through section 5?

EPA did not find that TBB was a may present chemical substance when it went through new chemicals review. If that had occurred under this draft of Section 5, some might have argued that EPA should therefore put TBB on the "low hazard," list (i.e., the no hazard list).

Now that TBB is an existing substance that has been around for awhile, could TBB be designated a low priority substance in EPA's view?

EPA does not agree that TBB is a chemical substance with no hazards (i.e., a “low hazard” chemical substance).
<< >>

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/24/2016 2:38:02 PM
To: jonathan_black@tomudall.senate.gov; Michal_Freedhoff@markey.senate.gov; Adrian_Deveny@merkley.senate.gov
Subject: Resend: Sen. Udall TSCA TA request on house section 4 (4-19)
Attachments: Udall.TSCA TA.Section 4 (HLC 4-19)..docx; ATT00001.htm

Resend with cover note:

Jonathan,
The attached TA responds to the request on section 4.

There do not appear to be any significant changes from the 4/18 HLC version other than the inclusion of the animal testing provisions from the 4/20 HLC version.

Attached is the list of Senate edits that were sent identifying which ones were made and which were not. Few were made. One suggestion from the Senate on that list that was not done, to replace globally the term "testing" with "protocols and methodologies", does not appear to have been done but would appear to introduce confusion if it was done since the HLC versions replace the term "standards" with "protocols and methodologies".

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser

U.S. EPA

Office of Congressional and Intergovernmental Relations

1200 Pennsylvania Ave., NW (1305A)

Washington, DC 20460

202-566-2753

From: "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov>
Date: April 24, 2016 at 10:34:38 AM EDT
To: "jonathan_black@tomudall.senate.gov" <jonathan_black@tomudall.senate.gov>,

"Michal_Freedhoff@markey.senate.gov" <Michal_Freedhoff@markey.senate.gov>,
"Adrian_Deveny@merkley.senate.gov" <Adrian_Deveny@merkley.senate.gov>
Subject: Sen. Udall TSCA TA request on house section 4 (4-19)

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/3/2016 2:10:36 AM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Re: partial REs

Got it - checking. Thanks,

Sven

On Apr 2, 2016, at 10:07 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Would something like this also work? Trying not to put a target on conditions of use.

(5) CHEMICAL SUBSTANCES WITH COMPLETED RISK ASSESSMENTS

With respect to chemical substances listed in the 2014 update to the TSCA Work Plan for Chemical Assessments for which EPA has published final risk assessments after June 1, 2014 and prior to the date of enactment of this Act, the Administrator may publish proposed and final rules under section 6(a) for the chemical substances that are consistent with the scope of the risk assessments for the chemical substances.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/11/2016 11:22:21 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Re: Urgent Sen. Markey TA request - House fees

Us too!

On Mar 11, 2016, at 5:49 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Ok – got it. sorry. just digging out now.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey
<image001.png><image002.png><image003.png><image004.jpg>

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Friday, March 11, 2016 4:00 PM
To: Freedhoff, Michal (Markey)
Subject: Fwd: Urgent Sen. Markey TA request - House fees

Michal-

This TA was based on the House bill as passed, but the concerns still remain for the House discussion draft.

Fees
Fees collected can be used only to "defray the cost of administering the provision of [TSCA] for which such fee is collected" (section 26(b)(1)). This means there would be no fee funding for any risk management rules, or for risk evaluations not requested by manufacturers. It also suggests that, for data submitted under § 4, the fees would cover only the cost of collecting the information, not of using the information to perform risk evaluations, which would occur under section 6(b). However, in setting the fees, 26(b)(1) provides that EPA is to take into account "the cost to the Administrator of reviewing such data." If the intent is that the fee cover the cost of review, as part of a section 6 risk evaluation or for other permissible purposes, the phrase limiting the fees to the cost of defraying the specific provision should be modified. More broadly, it is difficult to interpret and implement restrictions on the use of fees that are expressed in terms of the particular provision of TSCA that EPA can administer using the fees, since these do not necessarily align with recognized program areas or budget categories. A more descriptive statement of the program functions for which fees can be spent would be a help to EPA in adhering to these spending restrictions.

The bill would require EPA to set lower fees for small businesses, and it retains a provision requiring EPA to consider ability to pay. At the same time, the bill appears to require EPA to collect fees sufficient to cover the full cost of the services for which the fee is assessed. This is certainly true in the case of manufacturer-

requested risk evaluations (section 6(b)(4)(F)), and appears to be true generally (Section 26(b)(3)(C)). Is the intent that EPA would set fees for non-small businesses and businesses who are able to pay at an amount higher than the actual cost of the specific activities for which they are submitting fees, in order to make up any shortfall caused by reduction of fees paid by small businesses and businesses with limited ability to pay? If, so, this is in apparent conflict with the direction to avoid fees "more than reasonably necessary" from the larger manufacturers, as well as with the requirement to require full payment from manufacturers who request risk evaluations in section 6(b)(4)(F), which could include small manufacturers. If not, it is unclear how EPA can implement the statutory directive. More broadly, it is unclear whether the whole cost of a requested risk evaluation of a chemical substance must be borne by the one manufacturer who happens to request it, or whether EPA is expected to apportion the cost among the various manufacturers of the pertinent substance. Section 6(b)(4) seems to specify the former, but the language about reducing costs to small manufacturers would make more sense under the latter scenario, since the total cost could be set at what is "reasonably necessary," while simultaneously ensuring that small manufacturers of the chemical pay a relatively smaller share of the total cost.

The bill retains text in section 26(b)(1) of TSCA requiring EPA, in setting fees, to take into account the ability to pay "of the person required to submit the data" and the cost to EPA "of reviewing such data". This could be confusing, since the fee provisions under the bill would no longer apply only to submission of data.

To the extent that 26(b)(3)(C) describes a modified version of the process that EPA already uses to drawdown amounts available from the Treasury, it is unnecessary and potentially confusing. It also appears to bypass the requirement for OMB apportionment of funds to agencies. This confusion could be alleviated by removing this subsection, which would not negatively affect ability to implement the law.

Note that 26(b)(3)(D) will require EPA's fee collection/spending authority to be specifically re-authorized every year in EPA's appropriation act. Was that intentional?

In the report to Congress regarding EPA's capacity to carry out various functions (section 26(l)(1)(C)), EPA is required to report on its capacity to promulgate section 6(a) rules for chemicals subject to risk evaluation under 6(b), but not its capacity to promulgate section 6(a) rules for PBTs, as required by section 6(i). Was that intended?

From: "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>
Date: March 11, 2016 at 3:30:23 PM EST
To: "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov>
Cc: "Black, Jonathan (Tom Udall)" <Jonathan_Black@tomudall.senate.gov>, "Deveny, Adrian (Merkley)" <Adrian_Deveny@merkley.senate.gov>
Subject: TA request - House fees

Sven

Separate and apart from the policy questions related to what fees can be collected, what they can be used for, and how much the fees should be capped at, does EPA have workability or other issues with the House fees language, specifically the portions that create the fund, make funds available, etc? On the House proposal to the Senate, see esp pages 38 line 24 - Page 41 line 17. Basically we are trying to determine whether any of the operational elements of the fund in the House text pose challenges or limitations.

Thanks
M

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/21/2016 10:31:09 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: RE: Sen. Markey TSCA TA Request on Section 6 (4-20) Part 2

Interesting – will share - thanks

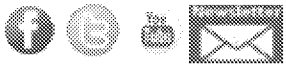
Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Thursday, April 21, 2016 6:30 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Markey TSCA TA Request on Section 6 (4-20) Part 2

Thanks – we caught the d2 one and have sent it back to the House. Inadvertent. Will look at the rest.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey



From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Thursday, April 21, 2016 6:27 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA Request on Section 6 (4-20) Part 2

Michal,
The attached TA responds to the request on section 6 (4-20). This is additional TA on section 6, on top of the TA we sent earlier today (Part 1). The TA is in 3 colors: green (the TA you already got, unchanged), yellow (new TA on the changes that we had not picked up on in our earlier run through), and blue (repeated TA from our comments on the previous version, so it's all in one place).

The most significant new issue (in yellow, p 25) is the observation that TSCA section 6(d)(2) – authorizing EPA to make section 6 proposals enforceable in certain circumstances – seems to have been stricken completely.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments. Please let me know if any questions. Thanks,

Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/19/2016 11:45:11 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Re: TSCA TA on HLC section 26 (4-18)

Ok- it combines three things-a response on the partial REs question, 3 points on the HLC version, and attached RLSO of the HLC version. I'm standing by all night and can call folks so let me know if questions. Thanks, Sven

On Apr 19, 2016, at 7:42 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

I am confused about some of your TA but will wait to print out before bugging you

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

From: Kaiser, Sven-Erik
Sent: Tuesday, April 19, 2016 7:39 PM
To: Freedhoff, Michal (Markey)
Subject: Re: TSCA TA on HLC section 26 (4-18)

We'll start on the remaining sections and be ready for any questions that come up later tonight. Thanks

On Apr 19, 2016, at 7:37 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

We haven't received anything more from house today, so hopefully you'll have an easier night!

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

From: Kaiser, Sven-Erik
Sent: Tuesday, April 19, 2016 7:36 PM
To: Freedhoff, Michal (Markey)
Subject: Re: TSCA TA on HLC section 26 (4-18)

Whew! Sorry for the delay. This is all we have for tonight (right now). Thanks,
Sven

On Apr 19, 2016, at 7:34 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Got it. Thank you.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

From: Kaiser, Sven-Erik
Sent: Tuesday, April 19, 2016 7:28 PM

To: Freedhoff, Michal (Markey)
Subject: TSCA TA on HLC section 26 (4-18)

Michal,
The TA below and attached responds to the request on HLC section 26 (4-18) including the question about partial risk evaluations.

We think that referencing the IQA in the manner suggested would make compliance with the IQA judicially reviewable in this context, setting a precedent in a statute with language allowing judicial review of IQA compliance. Up till now, IQA compliance has not been judicially reviewable.

Referencing the section 26 science provisions as you suggest would now subject those partial REs to standards that were not applicable at the time the risk assessments were completed. In essence, those requirements would become retroactively applicable to the completed risk assessments.

In that regard, we note that the new section 26 in the HLC version that we are still reviewing, as well as the last SLC version we have, still had the language at the end of the partial RE section (page 13, lines 18-19) that we had recommended striking in earlier TA. That language, "as in effect before such date of enactment", would subject the rulemakings on these substances to the current section 6 requirements (e.g., least burdensome), which we did not think was the intent of this provision.

Additional Items of major policy note:

Page 1, line 17 - Retention of older language that might necessitate keeping separate accounts for what money can be spent on which chemicals … must be the same chemical for which fees collected.

Page 3, lines 2-6 - Retention of older "provisions" language that creates an argument we can't spend fees on risk management or CBI work

Page 18, line 7 - narrowed the scope of one of the provisions that is supposed to prevent litigation over policies and procedures from being used to undermine previously completed risk evaluations, etc.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was

offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any questions. Thanks,

Sven

Sven-Erik Kaiser

U.S. EPA

Office of Congressional and Intergovernmental Relations

1200 Pennsylvania Ave., NW (1305A)

Washington, DC 20460

202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, April 19, 2016 5:01 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Cc: Deveny, Adrian (Merkley) <Adrian_Deveny@merkley.senate.gov>; Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>
Subject: partial REs

For after you finish with 5, and only if it is not going to delay you sending 26 (it is a 26 issue).

I am wondering if this is why House keeps baking least burdensome back into the partial RE language in 26. I'm not at all interested in the suggested CSAC approach as it won't exist in the right timeframe. I'd be interested in your thoughts on the IQA idea, but am thinking it probably makes sense to cite to the science language in 26 in the partial RE section and be done. I'd be interested in your thoughts

michal

Michal Ilana Freedhoff, Ph.D.

Director of Oversight & Investigations

Office of Senator Edward J. Markey

255 Dirksen Senate Office Building

Washington, DC 20510

202-224-2742

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Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 12/8/2016 4:52:43 PM
To: Poirier, Bettina (EPW [Bettina_Poirier@epw.senate.gov]; 'Albritton, Jason (EPW)' [Jason_Albritton@epw.senate.gov]; Fox, Thomas (EPW [Thomas_Fox@epw.senate.gov]
Subject: EPA Briefing on TSCA New Chemicals Review Program

Heads up that EPA is briefing congressional staff on the TSCA New Chemicals Review Program on Mon, Dec 12 at 2pm in 406 Dirksen. The briefing provides an opportunity to discuss progress under TSCA reform. It's intended as a bipartisan, bicameral briefing – I hope you can attend and please feel free to extend the invitation to interested staff. Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/2/2016 11:22:52 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Re: quick turnaround pls

Got it

On Mar 2, 2016, at 6:18 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Does this work

(4) RISK EVALUATION PROCESS AND DEADLINES.—

(A) <!--[if !supportLists]--><!--[endif]-->IN GENERAL.—The Administrator shall conduct risk evaluations pursuant to this paragraph to determine, without consideration of costs or other non-risk factors whether a chemical substance presents, in the absence of requirements under subsection (a), an unreasonable risk of injury to health or the environment under the conditions of use, including an unreasonable risk to a potentially exposed or susceptible population identified as relevant to the risk evaluation by the Administrator.

(B) <!--[if !supportLists]--><!--[endif]-->Not later than 1 year after enactment, the Administrator shall establish, by rule, a process to conduct risk evaluations in accordance with subparagraph (A).

(C) <!--[if !supportLists]--><!--[endif]-->The Administrator shall conduct and publish a risk evaluation, in accordance with the rule promulgated under subparagraph (B), for a chemical substance–

(i) <!--[if !supportLists]--><!--[endif]--> that has been identified under paragraph (2)(A) or designated under paragraph (1)(B)(i); and

(ii) <!--[if !supportLists]--><!--[endif]-->subject to subparagraph (F), that a manufacturer of the chemical substance has requested, in a form and manner and using the criteria prescribed by the Administrator in the rule promulgated under subparagraph (C), be subjected to a risk evaluation.

(D) <!--[if !supportLists]--><!--[endif]-->The Administrator shall, as soon as practicable and not later than 6 months of each designation of a high priority substance, publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use and the potentially exposed or susceptible populations the Administrator expects to consider.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
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202-224-2742

Connect with Senator Markey
<image001.png><image002.png><image003.png><image004.jpg>

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Wednesday, March 02, 2016 12:09 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA Request on Section 6 - quick unreasonable risk q

Michal,
This responds to your TA request on risk evaluations and unreasonable risk. Please let me know if any additional questions. Thanks,
Sven

Although there is too little detail to evaluate definitively, we have significant concerns with this proposed construct.

As you've described it, all risk management rules would still be subject to the current TSCA unreasonable risk standard, and EPA would still be limited by the same cost-benefit balancing analyses that have prevented effective action on chemicals in the past.

We also don't see the value in requiring EPA to issue a rule regarding risk evaluation with a preordained outcome: don't consider cost or other non-risk factors. This process will consume a significant amount of EPA time and resources, and delay the business of evaluating chemicals and protecting against identified risks. If Congress wants to preclude EPA from considering such factors in this context, the far more direct way to do so is by statutory directive.

Finally, if EPA is required to act by rule, commenters (and litigants) will likely argue that Congress must have intended EPA to have some discretion in the rulemaking, and will likely point to the authority to consider cost as part of the risk management rulemaking to argue that EPA should be able to factor cost in some fashion into the underlying safety standard. As such, this proposed approach seems likely to leave unsettled for a protracted period of time the most significant TSCA policy shift made in both bills.

Sven-Erik Kaiser
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202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, March 01, 2016 4:53 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Section 6 - quick unreasonable risk q

Here is a construct being discussed:

1) epa promulgates a rule for how risk evaluations are supposed to be conducted - study a chemical to decide whether it poses an unreasonable risk, and don't consider costs/non-risk factors - the unreasonable risk "fix" is made in the rule itself.

2) later in the section, we tell people to conduct a risk evaluation in accordance with the rule above, in order to figure out whether the substance poses an unreasonable risk, but I do NOT remove cost consideration in this place because of the reference to the RULE, which does require the fix.

Any concerns with this description re "unreasonable risk"?

Thanks
Michal

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/24/2016 2:34:38 PM
To: jonathan_black@tomudall.senate.gov; Michal_Freedhoff@markey.senate.gov; Adrian_Deveny@merkley.senate.gov
Subject: Sen. Udall TSCA TA request on house section 4 (4-19)
Attachments: Udall.TSCA TA.Section 4 (HLC 4-19)..docx; ATT00001.htm

Jonathan,
The attached TA responds to the request on section 4.

There do not appear to be any significant changes from the 4/18 HLC version other than the inclusion of the animal testing provisions from the 4/20 HLC version.

Attached is the list of Senate edits that were sent identifying which ones were made and which were not. Few were made. One suggestion from the Senate on that list that was not done, to replace globally the term "testing" with "protocols and methodologies", does not appear to have been done but would appear to introduce confusion if it was done since the HLC versions replace the term "standards" with "protocols and methodologies".

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser

U.S. EPA

Office of Congressional and Intergovernmental Relations

1200 Pennsylvania Ave., NW (1305A)

Washington, DC 20460

202-566-2753

From: "Black, Jonathan (Tom Udall)" <Jonathan_Black@tomudall.senate.gov>
Date: April 23, 2016 at 5:54:20 PM EDT
To: "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov>
Cc: "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>, "Deveny, Adrian (Merkley)"

<Adrian_Deveny@merkley.senate.gov>
Subject: Section 4 review...

Sven, perhaps the same exercise for Section 4 that you just did for Section 26. Attached below are the changes we sent to House folks this week and to HLC, but they appear not to have been made.

Take a look at Section 4 to see if anything catches your eye beyond the failure to make these changes. Thanks.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/15/2016 9:39:06 PM
To: Deveny, Adrian (Merkley) [Adrian_Deveny@merkley.senate.gov]
Subject: Re: Sen. Merkley TSCA TA on state waiver.

Adrian,
Got it, working on it for tonight. Thanks,
Sven

On Apr 15, 2016, at 5:18 PM, Deveny, Adrian (Merkley) <Adrian_Deveny@merkley.senate.gov> wrote:

I hate to ask but is it at all possible to get a response tonight to this?

From: Deveny, Adrian (Merkley)
Sent: Friday, April 15, 2016 5:12 PM
To: 'Kaiser, Sven-Erik'
Subject: RE: Sen. Merkley TSCA TA on state waiver.

Thank you for this. Working from your language now, it looks it will not be possible to include "prioritization" or "is otherwise related". So, now my question is, which of these two options offers the most broad scope of inclusion for state rules to trigger eligibility for a waiver?

Option 1:

> (B) the State or political subdivision of the State has promulgated a final administrative action or published a proposed administrative action, prior to the date on which the Administrator initiated a risk evaluation to be conducted on such chemical substance in accordance with section 6(b)(4)(D), that is for the assessment or management related to the effects of exposure to such chemical substance, and has submitted such final or proposed action to the Administrator.

Option 2:

> (B) the State or political subdivision of the State has promulgated a final administrative action or published a proposed administrative action, prior to the date on which the Administrator initiated a risk evaluation to be conducted on such chemical substance in accordance with section 6(b)(4)(D), that is related to the effects of exposure to such chemical substance, and has submitted such final or proposed action to the Administrator.

"(2) REQUIRED EXEMPTIONS.—Upon application of a State or political subdivision of a State, the Administrator shall exempt from subsection (b) a statute or administrative action of a State or political subdivision of a State that relates to the effects of exposure to a chemical substance under the conditions of use if the Administrator determines that—

> **"..."**
>
> **(B) the State or political subdivision of the State has promulgated a final administrative action or published a proposed administrative action, prior to the date on which the Administrator published the scope of the risk evaluation to be conducted on such chemical substance in**

accordance with section 6(b)(4)(D), that is for the prioritization, assessment, or management of such chemical substance or is otherwise related to the effects of exposure to such chemical substance, and has submitted such final or proposed action to the Administrator.

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Friday, April 15, 2016 2:00 PM
To: Deveny, Adrian (Merkley)
Subject: Sen. Merkley TSCA TA on state waiver.

Adrian,
This responds to the request on state preemption waivers.

Can EPA please take a look at the language in red below. The objective of this language is to a provide the opportunity for a state to obtain a waiver from pause pre-emption when essentially when the state has initiated its own rulemaking process to restrict a chemical prior to EPA. Some states do this with one rulemaking, and others do it with multiple rules in sequence, but the idea is that if a state has published a draft/proposed rule to prioritize a chemical prior to the start of the pause, then the final rule that does restrict the chemical can obtain an automatic waiver to be implemented during the pause.

First, does this language accomplish this objective?

No, because it doesn't clearly account for the fact that there are two different actions at issue: First, there is the action for which the state is seeking a preemption waiver; Second, there is the proposed or final *preliminary* action that predated EPA's scope publication, which is the basis for the state being entitled to the preemption waiver. What links the actions is that they relate to the same chemical substance, but there is no such linking language in the current draft. Also, the reference to a "draft" action should really be a reference to a "proposed" action. Here's the revised language, in context:

"(2) REQUIRED EXEMPTIONS.—Upon application of a State or political subdivision of a State, the Administrator shall exempt from subsection (b) a statute or administrative action of a State or political subdivision of a State that relates to the effects of exposure to a chemical substance under the conditions of use if the Administrator determines that—

...

(B) the State or political subdivision of the State has promulgated a final administrative action or published a proposed administrative action, prior to the date on which the Administrator published the scope of the risk evaluation to be conducted on such chemical substance in accordance with section 6(b)(4)(D), that is for the prioritization, assessment, or management of such chemical substance or is otherwise related to the effects of exposure to such chemical substance, and has submitted such final or proposed action to the Administrator.

Second, if I strike the words "for prioritization, assessment, management or other action", would it achieve the same objective? (allowing precursor draft/final rules on prioriziation and assessment completed before EPA's scoping to provide a waiver from the puase to the final state rule to restrict a chemical)

Deleting the words would make the passage less likely to function in the manner you intend. The phrase "prioritization, assessment, or management" helps to illustrate what you mean by an action that is "related to the effects of exposure." Even though the illustrative list is just a subset of what is already included under the heading of "related to," an illustrative list helps to guard against courts later construing "related to" more narrowly than you intend (e.g., deciding that prioritization can't be related to the effects of exposure because the state hasn't yet definitively figured out what those effects are at the stage of prioritization).

Section 18(f)(2) Required Exemptions.—

"(2) REQUIRED EXEMPTIONS.—Upon application of a State or political subdivision of a State, the Administrator shall exempt from subsection (b) a statute or administrative action of a State or political subdivision of a State that relates to the effects of exposure to a chemical substance under the conditions of use if the Administrator determines that—

"(A) (i) compliance with the proposed requirement of the State or political subdivision of the State would not unduly burden interstate commerce in the manufacture, processing, distribution in commerce, or use of a chemical substance;

"(ii) compliance with the proposed requirement of the State or political subdivision of the State would not cause a violation of any applicable Federal law, rule, or order; and

"(iii)the State or political subdivision of the State has a concern about the chemical substance or use of the chemical substance based in peer-reviewed science; or

(B) the State or political subdivision of the State has promulgated a final administrative action or published a proposed administrative action on a chemical substance for prioritization, assessment, management, or other action related to the effects of exposure to the chemical substance prior to the date on which the Administrator published the scope of the risk evaluation to be conducted on the chemical substance in accordance with section 6(b)(4)(D), and has submitted such draft or final action to the Administrator."

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any questions. Thanks,

Sven

Sven-Erik Kaiser

U.S. EPA

Office of Congressional and Intergovernmental Relations

1200 Pennsylvania Ave., NW (1305A)

Washington, DC 20460

202-566-2753

From: "Deveny, Adrian (Merkley)" <Adrian_Deveny@merkley.senate.gov>
Date: April 14, 2016 at 9:44:32 PM EDT
To: "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov>
Subject: TA on waiver

Sven

Can EPA please take a look at the language in red below. The objective of this language is to a provide the opportunity for a state to obtain a waiver from pause pre-emption when essentially when the state has initiated its own rulemaking process to restrict a chemical prior to EPA. Some states do this with one rulemaking, and others do it with multiple rules in sequence, but the idea is that if a state has published a draft/proposed rule to prioritize a chemical prior to the start of the pause, then the final rule that does restrict the chemical can obtain an automatic waiver to be implemented during the pause.

First, does this language accomplish this objective?

Second, if I strike the words "for prioritization, assessment, management or other action", would it achieve the same objective? (allowing precursor draft/final rules on priorizlation and assessment completed before EPA's scoping to provide a waiver from the puase to the final state rule to restrict a chemical)

Section 18(f)(2) Required Exemptions.—

"(2) REQUIRED EXEMPTIONS.—Upon application of a State or political subdivision of a State, the Administrator shall exempt from subsection (b) a statute or administrative action of a State or political subdivision of a State that relates to the effects of exposure to a chemical substance under the conditions of use if the Administrator determines that—

"(A) (i) compliance with the proposed requirement of the State or political subdivision of the State would not unduly burden interstate commerce in the manufacture, processing, distribution in commerce, or use of a chemical substance;

"(ii) compliance with the proposed requirement of the State or political subdivision of the State would not cause a violation of any applicable Federal law, rule, or order; and

"(iii)the State or political subdivision of the State has a concern about the chemical substance or use of the chemical substance based in peer-reviewed science; or

(B) the State or political subdivision of the State has promulgated a final administrative action or published a proposed administrative action on a chemical substance for prioritization, assessment, management, or other action related to the effects of exposure to the chemical substance prior to the date on which the Administrator published the scope of the risk evaluation to be conducted on the

chemical substance in accordance with section 6(b)(4)(D), and has submitted such draft or final action to the Administrator."

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/5/2016 9:23:27 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Re: section 4

Yes

On Apr 5, 2016, at 5:20 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Yes. Noon possible?

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

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<image001.png><image002.png><image003.png><image004.jpg>

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Tuesday, April 05, 2016 5:20 PM
To: Freedhoff, Michal (Markey)
Subject: Re: section 4

Michal- we are getting to the Senate counter to the House section 4, aiming for something tomorrow- okay? Thanks, Sven

On Apr 5, 2016, at 2:34 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Sven

Attached is a new Section 4 that we need TA on. Generally, it can be described as:

- <!--[if !supportLists]--><!--[endif]-->Existing TSCA 4(a)(1) and 4(a)(2) (mostly)
- <!--[if !supportLists]--><!--[endif]-->In addition to that, Senate text on other circumstances that allow testing, by rule or order or consent agreement
- <!--[if !supportLists]--><!--[endif]-->Other changes to things like ITC and 4(f) that have been discussed/proposed by various parties
- <!--[if !supportLists]--><!--[endif]-->All (I hope) the conforming changes the House offer removed or didn't do

Please give it a careful read and let us know of any issues.

Senate colleagues – note I did not strike and replace the animal testing language but just bracketed it to reflect ongoing discussions. Let me know if you want a different approach there.

Thanks
michal
<4-04-05-16SENATECOUNTERTOHOUSE.doc>

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/13/2016 8:27:19 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: RE: PBT question - why wouldn't something like this work? House did this

Michal – got it – checking. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Wednesday, April 13, 2016 4:20 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: PBT question - why wouldn't something like this work? House did this

(a) SCOPE OF REGULATION. If the Administrator determines in accordance with subsection (b)(4)(A) that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents an unreasonable risk of injury to health or the environment, OR DESIGNATES THE SUBSTANCE UNDER THE PBT PARA the Administrator shall by rule, and subject to section 18 and in accordance with subsection (c)(2), apply one or more of the following requirements to such substance or mixture to the extent necessary so that the chemical substance does not present such a risk under the conditions of use.:

Michal Ilana Freedhoff, Ph.D.
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202-224-2742

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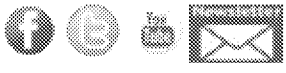

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 11/17/2016 1:21:21 PM
BCC: Distefano, Nichole [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31d32a3a3a9e4591b5fdfc3eb96e8b78-Distefano,]; Brown, Tristan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2524f58c2f0442cbbd025cdcbd4d1f7e-Hilton, Tri]; Schmit, Ryan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7077ecbac4914a00ad465398f92bbe78-Schmit, Ryan]; Scheifele, Hans [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dd4c2e03967741c2a8d643869c0681db-HScheife]; Pierce, Alison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036313052e20472ca55f7733de62f969-APierce]; Strauss, Linda [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=301660ea0f7845769db2210317516451-Strauss, Linda]; Jackson, Ryan (Inhofe [Ryan_Jackson@inhofe.senate.gov]; 'Albritton, Jason (EPW)' [Jason_Albritton@epw.senate.gov]; Poirier, Bettina (EPW [Bettina_Poirier@epw.senate.gov]; Fox, Thomas (EPW [Thomas_Fox@epw.senate.gov]; Fruci, Jean [Jean.Fruci@mail.house.gov]; brendan.larkin@mail.house.gov; 'Deveny, Adrian (Merkley)' [Adrian_Deveny@merkley.senate.gov]; Zipkin, Adam (Booker [Adam_Zipkin@booker.senate.gov]; Enderle, Emily (Whitehouse [Emily_Enderle@whitehouse.senate.gov]; Wojciechowski, Adrienne (Judiciary-Dem) [Adrienne_Wojciechowski@Judiciary-dem.senate.gov]; laura_gillam@carper.senate.gov
Subject: Notification: EPA Announces Public Meeting on TSCA New Chemicals Review - December 14

Heads up that EPA is holding a meeting to update the public on changes to the TSCA New Chemicals Review Program on Weds, Dec 14. EPA will describe the review process for new chemicals under the amended statute, as well as discuss issues, challenges, and opportunities that the agency has identified in the first few months of implementation. Interested parties will have the opportunity to provide input on their experiences with the New Chemicals Review Program, including submittal of pre-manufacture notices (PMNs), microbial commercial activities notices (MCANs), and significant new use notices (SNUNs), under section 5 of the law. Information obtained during this meeting and from submitted written comments will be considered as EPA implements the new requirements and increases efficiency in its review process under TSCA.

Register for the meeting in advance: We ask that you please register for this meeting by December 13, 2016.

Date and Time: Wednesday, December 14, 2016, from 9:00 a.m. to 12:00 p.m.

Location: The Ronald Reagan Building and International Trade Center, Polaris Room, 1300 Pennsylvania Avenue Northwest, Washington, DC 20004

Docket number to submit written comments: EPA-HQ-OPPT-2016-0658 (Docket will be open prior to and remain open after the meeting.)

Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/8/2016 9:29:08 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TA request on PBTs- followup

Michal – this TA responds to the followup request on PBTs.

QUESTION: For context, we are working through the potential for a hybrid House-Senate PBT provision for section 6 that would downselect some of the high pbts from the TSCA workplan and send them straight to risk management. In addition to metals/metal compounds, there is a suggestion that these 3 should perhaps be excluded because EPA is already looking at them enough to basically be able to say "they've already done a bunch of what would go into the risk evaluation, so they should continue on the path they're on". That rationale seems perhaps to be solid for the first 2 – do you agree? What about the 3rd? would you need that data to go to risk management anyway?

Response: All three should continue on the risk evaluation path.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>
Date: April 8, 2016 at 4:11:59 PM EDT
To: "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Markey TSCA TA request on PBTs

Thanks. For context, we are working through the potential for a hybrid House-Senate PBT provision for section 6 that would downselect some of the high pbts from the TSCA workplan and send them straight to risk management. In addition to metals/metal compounds, there is a suggestion that these 3 should perhaps be excluded because EPA is already looking at them enough to basically be able to say "they've already done a bunch of what would go into the risk evaluation, so they should continue on the path they're on". That rationale seems perhaps to be solid for the first 2 – do you agree? What about the 3rd? would you need that data to go to risk management anyway?

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
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255 Dirksen Senate Office Building
Washington, DC 20510
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From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Friday, April 08, 2016 4:06 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA request on PBTs

Michal,
This responds to the TA request on PBTs.

Chlorinated paraffins:

The medium and long-chain chlorinated paraffins are being reviewed under Section 5. (Short-chain CPs have been taken off the market). Because of the high level of interest in these chemicals, EPA published an assessment in Dec. 2015 with a request for additional information on downstream uses of the chemicals. The comment period closed on March 23d, and we are currently reviewing comments.

HBCD:

EPA published a Work Plan Problem Formulation for comment in August 2015. We are developing a draft assessment and hope to publish this summer.

D4Siloxane:

We are not assessing at this time. We entered into an Enforceable Consent Agreement under section 4 to obtain monitoring and environmental fate data to inform an assessment. The work is underway now through fall to develop the data and we expect to receive it in 2017.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
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202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Friday, April 08, 2016 1:53 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: TA request on PBTs

Chlorinated paraffins

HBCD
D4siloxane

For these - I'm told EPA is doing risk assessment-like work on these. How far into the process are you for each of these?

Thx
M

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/3/2016 1:38:11 AM
To: Michal_Freedhoff@markey.senate.gov
Subject: Fwd: Revised partial risk evaluation and management language
Attachments: Markey.TSCA TA.Proceeding in phases pared down.docx; ATT00001.htm

Resend, please confirm attachment went through. Thanks,
Sven

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Re-title Section 26(j) as follows:

(j) POLICIES, PROCEDURES, ~~AND~~ GUIDANCE, AND CHEMICAL SUBSTANCES WITH COMPLETED RISK ASSESSMENTS

Renumber 26(j)(5) as 26(j)(6), and add the following after 26(j)(4):

(5) CHEMICAL SUBSTANCES WITH COMPLETED RISK ASSESSMENTS

(A) With respect to chemical substances listed in the 2014 update to the TSCA Work Plan for Chemical Assessments for which EPA has completed risk assessments on or after XXX but prior to the date of enactment of the TSCA Modernization Act of 2015, the Administrator may ~~conduct risk evaluations under section 6(b)(4) and~~ publish proposed and final rules under section 6(a) for the uses assessed, as appropriate~~,~~ based on the results of those risk assessments, notwithstanding the fact that the risk assessments the Administrator has completed for such chemical substances did not evaluate all conditions of use. ~~Any such risk evaluations shall evaluate the risks from the uses of the chemical substances that the Administrator assessed in the completed TSCA Work Plan risk assessments, to determine whether the chemical substances present an unreasonable risk of injury to health or the environment under those uses in accordance with section 6(b)(4), and any such rules shall ensure that the chemical substances do not present an unreasonable risk of injury to health or the environment, as that term is used in section 6(b)(4)(A), under those uses. In conducting such risk evaluations and proposing and promulgating such rules, the Administrator shall follow the deadlines and other requirements of sections 6(b)(4) and 6(c), as applied to the uses addressed in the rulemakings, with the deadlines running from the date of enactment of the TSCA Modernization Act of 2015.~~

~~(B) The Administrator shall subject any conditions of use that had not been considered in the completed risk assessments of these chemical substances to the processes and requirements of section 6(a), 6(b), and 6(c), as applied to those conditions of use.~~

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/11/2016 11:21:57 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Re: Sen. Markey TSCA TA Request on section 14

Got it - checking.

On Mar 11, 2016, at 5:48 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Actually I was looking for TA on HOUSE section 14 if you have it. Thanks.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

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-----Original Message-----
From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Friday, March 11, 2016 5:07 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA Request on section 14

Michal,
This responds to your TA request on section 14. You already have our comprehensive TA on the Senate bill as passed including TA on section 14 - attached is a pullout from that on section 14. We didn't see anything major in the new draft, spotted some potential glitches and it needs conforming changes that we haven't had a chance to pull together. Please let me know if any additional questions. Thanks, Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

-----Original Message-----
From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Friday, March 11, 2016 4:37 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Re: TA support

Thanks. Those sections likely next week now. I think we are headed to 14 next - if you have TA on House 14 prepared pls send.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations Office of Senator Edward J. Markey (D-MA)
Original Message

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/21/2016 10:27:19 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TA Request on Section 6 (4-20) Part 2
Attachments: Markey TSCA TA Section 6 (HLC 4-20) Part 2.docx

Michal,
The attached TA responds to the request on section 6 (4-20). This is additional TA on section 6, on top of the TA we sent earlier today (Part 1). The TA is in 3 colors: green (the TA you already got, unchanged), yellow (new TA on the changes that we had not picked up on in our earlier run through), and blue (repeated TA from our comments on the previous version, so it's all in one place).

The most significant new issue (in yellow, p 25) is the observation that TSCA section 6(d)(2) – authorizing EPA to make section 6 proposals enforceable in certain circumstances – seems to have been stricken completely.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments. Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
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1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

SEC. ll. PRIORITIZATION, RISK EVALUATION, AND REGULATION OF CHEMICAL SUBSTANCES AND MIXTURES.

(a) AMENDMENTS.—Section 6 of the Toxic Substances Control Act (15 U.S.C. 2605) is amended—

(1) by striking the section heading and inserting "**PRIORITIZATION, RISK EVALUATION, AND REGULATION OF CHEMICAL SUBSTANCES AND MIXTURES**";

(2) in subsection (a)—

(A) by striking "finds that there is a reasonable basis to conclude that" and inserting "determines in accordance with subsection (b)(4)(A)";

(B) by inserting "or ~~designates~~that a chemical sub stance is a substance ~~under~~ described in subsection ~~(b)(4)~~ *section 6PBT(d)(h),*" after "health or the environment,";

(C) by inserting "and subject to section 18, and in accordance with subsection (c)(2)," after "shall by rule";

(D) by striking "to protect adequately against such risk using the least burdensome requirements" and inserting "so that the chemical substance no longer presents such risk";

Commented [A1]: EPA TA: Should probably add "that" after b4A

Commented [A2]: EPA TA: Suggest taking out reference to PBT in 6(a), so as not to cause confusion about what the rulemaking standard is, which is handled in 6(h).

(E) by inserting "or otherwise restricting" after "prohibiting" in paragraph (2)(A);

(F) by inserting "minimum" before "warnings" both places it appears in paragraph (3);

(G) by striking "and monitor or conduct tests" and inserting "or monitor or conduct tests pursuant to section 4" in paragraph (4); and

(H) in paragraph (7)—

(i) by striking "such unreasonable risk of injury" and inserting "such determination"; and

(ii) by striking "such risk of injury" and inserting "such determination";

(3) by amending subsection (b) to read as follows:

"(b) RISK EVALUATIONS.—

"(1) PRIORITIZATION FOR RISK EVALUATIONS.—

"(A) ESTABLISHMENT OF PROCESS.—Not later than 1 year after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall establish, by rule, a risk-based screening process, including criteria for designating chemical

Commented [A3]: Earlier EPA TA: It is more important that the "otherwise restricting" appear in (1) than (2), if the intent is to allow for general regulation of manufacture, processing and distribution.

Commented [A4]: Earlier EPA TA: Inclusion of "minimum" here but not for other requirements might suggests that other requirements are ceilings.

Commented [A5]: EPA TA: This will suggest that EPA must follow any applicable section 4 requirements, as well as section 6 requirements, in imposing test requirements.

substances as high-priority substances for risk evaluations or low-priority substances for which risk evaluations are not warranted at the time. The process to designate the priority of chemical substances shall include a consideration of the hazard and exposure potential of a chemical substance or categoriesa category of chemical substances (including consideration of persistence and bioaccumulation, potentially exposed or susceptible subpopulations and storage near significant sources of drinking water), the conditions of use or significant changes in the conditions of use of the chemical substance, and the volume or significant changes in the volume of the chemical substance manufactured or processed.

"(B) IDENTIFICATION OF PRIORITIES FOR RISK EVALUATION.—

"(i) HIGH-PRIORITY SUBSTANCES.—The Administrator shall designate as a high-priority substance an active chemical substance that the Administrator concludes, without consideration of costs or other nonrisk factors, may present an unreasonable risk of injury to health or the environment, ~~without consideration of costs or~~

Commented [A6]: EPA TA: Responsive to prior EPA TA.

Commented [A7]: Earlier EPA TA: Redundant and potentially confusing as to meaning of conditions of use.

Commented [A8]: EPA TA: Moving the risk-only proviso closer to the key verb seems helpful.

other nonrisk factors, because of potential hazard

and a potential route of exposure under the conditions of use, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator.

"(ii) LOW-PRIORITY SUBSTANCES.—The Administrator shall designate as a low-priority substance a chemical substance with respect to which the Administrator concludes ~~has~~ based on information sufficient to establish, without consideration of costs or other nonrisk factors, that the chemical substance is not likely to present an unreasonable risk ~~of injury~~ to health or ~~the environment, without consideration of costs or other nonrisk factors,~~ environment under the conditions of use, ~~including~~including an unreasonable risk to a ~~potentially~~potentially exposed or susceptible ~~subpopulation~~ subpopulation identified as relevant by the ~~Administrator~~Administrator.

Commented [A9]: EPA TA: Missing a word here. Sufficient to establish the conclusion.?

Commented [A10]: EPA TA: Responsive to prior EPA TA

"(iii) INACTIVE SUBSTANCES.—The Administrator may designate an inactive chemical substance as a high-priority substance if the Administrator concludes that such substance has not been subject to a regulatory or other enforceable action by

the Administrator to ban or phase out the

substance and has the potential for high hazard and widespread exposure, or has been subject to a regulatory or other enforceable action by the Administrator to ban or phase out the substance and with respect to which there exists the potential for residual high hazards ~~or~~and widespread ~~ex-~~posures ~~exposures~~ not otherwise addressed by the regulatory or other action.

Commented [A11]: EPA TA: Standard is now the same whether or not the substance has been made subject to a ban/phaseout.

"(2) INITIAL RISK EVALUATIONS AND SUBSEQUENT DESIGNATIONS OF HIGH- AND LOW-PRIORITY SUBSTANCES.—

"(A) INITIAL RISK EVALUATIONS.—Not later than 180 days after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall ensure that risk evaluations are being conducted on at least 10 chemical substances drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments (of which at least 6 shall also be chemical substances that have a Persistence and Bioaccumulation Score of 3).

"(B) ADDITIONAL RISK EVALUATIONS.—

Not later than three and one half years after

the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall ensure that risk evaluations are being conducted on at least 20 high-priority substances and that at least 20 chemical substances have been designated as low-priority substances, subject to the limitation that at least 50 percent of all chemical substances on which risk evaluations are being conducted by the Administrator are drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments (of which at least one half shall also be chemical substances that have a Persistence and Bioaccumulation Score of 3).

"(C) CONTINUING DESIGNATIONS AND RISK EVALUATIONS.—The Administrator shall continue to designate priority substances and conduct risk evaluations in accordance with subsection (b)(3)(D), subject to the limitation described in subparagraph (B), until all substances drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments (including all such chemical substances that

Commented [A12]: EPA TA: Related to the next comment, we believe this comma should be stricken. As we understand this provision, the intent is to say that the continuing prioritization and risk evaluations shall be subject to the limitation in (E) until all WP chems have undergone risk evaluation. In other words, we understand the phrase "until all substances drawn from the WP have undergone risk evaluations" as delimiting only the time period during which the limitation in (B) applies. With the comma, the text indicates that "until all substances drawn from the WP have undergone risk evaluations" is part of the delimitation of the overall duty to continue to prioritize and evaluate. Note that, even with the fix we suggest, over time EPA will not be able to comply with the requirement to comply with B until all WP chems have been evaluated, because B requires that a least half the WP chems undergoing risk evaluation be PBT 3s until all work plan chemicals are done, and EPA presumably will run out of such chemicals well before then.

have a Persistence and Bioaccumulation Score

of 3) have undergone risk evaluations and until

Commented [A13]: EPA TA: Prior EPA TA was to replace the "and" with a comma so that the whole phrase "subject to, [. . .] have undergone risk evaluations" is set off as a clause. The comma seems to still be missing.

Commented [A14]: Earlier TA: Awkward that all WP chems must undergo prioritization but must be prioritized as high. In addition, EPA will not be able to comply with this provision over time, since it seems to require that half of work plan chemicals undergoiong risk evaluation be PBTs until all work plan chemicals are done, which won't be possible.

the priority of all active chemical substances has been designated, at a pace consistent with the ability of the Administrator to complete risk evaluations in accordance with the deadlines under paragraph (4)(G).

"(D) PREFERENCE.—In designating high-priority substances, the Administrator shall give preference to—

"(i) chemical substances that are listed in the 2014 update of the TSCA Work Plan for Chemical Assessments as having a Persistence and Bioaccumulation Score of 3; and

"(ii) chemical substances that are listed in the 2014 update of the TSCA Work Plan for Chemical Assessments that are known human carcinogens and have high acute and chronic toxicity.

"(E) METALS AND METAL COMPOUNDS.—In identifying priorities for risk evaluation and conducting risk evaluations of metals and metal compounds, the Administrator shall use the Framework for Metals Risk As-

sessment of the Office of the Science Advisor, Risk Assessment Forum, and dated March

2007 (or a successor document), and may use other applicable information consistent with the best available science.¿

"(3) INFORMATION REQUEST AND REVIEW AND PROPOSED AND FINAL PRIORITIZATION DESIGNATIONS.—

"(A) DEADLINE; PROCESS.—The Administrator shall, in the rulemaking required under paragraph (1)(A), ensure that the time required to make a priority designation of a chemical substance be no longer than 1 year, and that the process for such designations includes—

"(i) a requirement that the Administrator request interested persons to submit relevant information on a chemical substance that the Administrator is proposing to prioritize;

"(ii) a requirement that the Administrator publish each proposed designation of a chemical substance as a high- or low-priority substance, along with an identification of the information, analysis and basis used to make the proposed designations,

take public comment on each such proposed designation, and publish all final

designations after the close of the public comment period; and

"(iii) a process by which the Administrator may extend the deadline under this subparagraph for up to six months in order to receive or evaluate information required to be submitted in accordance with section 4(a)(2), subject to the limitation that if the information available to the Administrator at the end of such an extension remains insufficient to enable the designation of the chemical substance as a low-priority substance, the Administrator shall designate the chemical substance as a high-priority substance.

Commented [A15]: x-ref check

"(B) RISK EVALUATION INITIATION.—Upon designating a chemical substance as a high-priority substance, the Administrator shall initiate a risk evaluation on the substance.

"(C) REVISION.—The Administrator may revise the designation of a low-priority substance based on information made available to the Administrator.

"(D) ONGOING DESIGNATIONS.—The Administrator shall designate at least one high-

priority substance upon the completion of each risk evaluation (other than risk evaluations for chemical substances designated under paragraph (4)(C)(ii)).

"(E) PRIORITY DESIGNATION CONSIDERATIONS.—The Administrator shall designate the priority of chemical substances under this subsection at a pace that allows for appropriate notice and comment on each individual chemical substance.

"(4) RISK EVALUATION PROCESS AND DEADLINES.—

"(A) IN GENERAL.—The Administrator shall conduct risk evaluations pursuant to this paragraph to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use.

Commented [A16]: Earlier TA: We think this works, but it would be simpler if this just said "The Administrator shal designate at least one high-priority substance upon the completion of each risk evaluation for a high-priority substance". Isn't that the point? And since at least 20 HP substances must be undergoing risk eval under 2B with 3-1/2 years, doesn't that permanently set the floor at 20 (plus industry-initiated)?

Commented [A17]: **EPA TA:** This new paragraph weakens the enforceability of the prioritization deadlines and throughput requirements in (b)(2) and (b)(3), by suggesting that they are all subject to adjustment if the Administrator finds that slower pace or throughput is appropriate to accommodate the notice and comment process. Comment periods are usually only on the order of 30-90 days, so it is unclear what concern this is intended to address.

Commented [A18]: Earlier TA: Would be ideal to add "will present"

Commented [A19]: Earlier TA: Reference to "under the conditions of use" should be moved up to follow "without consideration of costs or other nonrisk factors."

This conforms to the prior recitations of this litany, and avoids the potential confusion that the "conditions of use" caveat only modifies the application to vulnerable populations

"(B) ESTABLISHMENT OF PROCESS.—Not later than 1 year after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall establish, by rule, a process to conduct risk evaluations in accordance with subparagraph (A).

"(C) REQUIREMENT.—The Administrator shall conduct and publish risk evaluations, in

accordance with the rule promulgated under subparagraph (B), for a chemical substance—

"(i) that has been identified under paragraph (2)(A) or designated under paragraph (1)(B)(i); and

"(ii) subject to subparagraph (E), that a manufacturer of the chemical substance has requested, in a form and manner and using the criteria prescribed by the Administrator in the rule promulgated under subparagraph (B), be subjected to a risk evaluation.

"(D) SCOPE.—The Administrator shall, as soon as practicable and not later than 6 months after each designation of a high-priority substance, publish the scope of the risk evaluation

Commented [A20]: EPA TA: Change in response to prior EPA TA.

to be conducted, including the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider.

"(E) LIMITATION AND CRITERIA.—

"(i) PERCENTAGE REQUIREMENTS.—

The Administrator shall ensure that, of the number of chemical substances that undergo a risk evaluation under clause (i) of subpara-

Commented [A21]: EPA TA: This is the wrong denominator. You are asking here what % of the EPA-initiated chemicals are industry requests.

We're pretty sure you mean to be asking here what % of the total chemicals (whether EPA-initiated or industry requested) are in fact industry requested.

graph (C), the percentage of chemical substances undergoing a risk evaluation under clause (ii) of subparagraph (C) is—

"(I) not less than 25 percent, if sufficient requests are made under clause (ii) of subparagraph (C); and

~~"(II) not more than 50 percent~~50 percent.

"(ii) REQUESTED RISK EVALUATIONS.—Requests for risk evaluations under subparagraph (C)(ii) shall be subject to public notice and comment and to the payment of fees pursuant to section 26(b)(3)(D), and the Administrator shall ~~allocate resources for such risk evaluations consistent with the percentage requirements specified in clause (i) and shall~~ not expedite or otherwise provide special ~~treatment~~treatment to such risk evaluations.

Commented [A22]: EPA TA: Edit responsive to prior EPA TA

"(iii) PREFERENCE.—In deciding whether to grant requests under subparagraph (C)(ii), the Administrator shall give preference to requests for risk evaluations on chemical substances for which the Administrator determines that restrictions

imposed by 1 or more States have the potential to have a significant impact on interstate commerce or health or the environment.

"(iv) EXCEPTIONS.—(I) Chemical substances for which requests have been granted under subparagraph (C)(ii) and that are not drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments shall not be subject to section 18(b).

"(II) Requests for risk evaluations on chemical substances which are made under subparagraph (C)(ii) and that are drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments shall be granted at the discretion of the Administrator and not be subject to clause (i)(II).

"(F) REQUIREMENTS.—In conducting a risk evaluation under this subsection, the Administrator shall—

"(i) integrate and assess available information on hazards and exposures for the conditions of use of the chemical substance, including information that is rel-

evant to specific risks of injury to health or the environment and information on potentially exposed or susceptible subpopulations identified as relevant by the Administrator;

"(ii) describe whether aggregate or sentinel exposures to a chemical substance under the conditions of use were considered, and the basis for that consideration;

~~"(iii) not consider information on cost~~ and costs or other nonrisk factors not directly related to health or the environment;

"(iv) take into account, where relevant, the likely duration, intensity, frequency, and number of exposures under the conditions of use of the chemical substance; and

Commented [A23]: EPA TA: Prior EPA TA was to conform this to the standard recitation.

"Costs or other nonrisk factors not directly related to health or the environment" is still a non-standard recitation.

As edited, this now suggests that certain costs and certain nonrisk factors **CAN BE** considered, namely, the costs and nonrisk factors that are "directly related to health or the environment."

"(v) describe the weight of the scientific evidence for the identified hazard and exposure.

"(G) DEADLINES.—The Administrator—

"(i) shall complete a risk evaluation for a chemical substance as soon as practicable, but not later than 3 years after the date on which the Administrator initiates a

Commented [A24]: Earlier comment: Should be "the"

risk evaluation under paragraph ~~(1)(B)(i), (2), or~~ (4)(C);

and

"(ii) may extend the deadline for a risk evaluation for not more than 1 year, if information relating to the chemical substance required to be developed in a rule, order, or consent agreement under section 4 has not yet been submitted to the Administrator, or if such information has been submitted to the Administrator within the time specified in the rule, order, or consent agreement and on or after the date that is 120 days before the expiration of the deadline described in clause (i).

"(H) NOTICE AND COMMENT.—The Administrator shall provide no less than 30 days public notice and an opportunity for comment

Commented [A25]: EPA TA: Edits responding to prior EPA TA.

Commented [A26]: Earlier TA: Might be more precise to say "is required to be developed in a rule, order of consent agreement under section 4 after the deadline." As drafted, the deadline could be extended if someone missed the test rule/order deadline.

on a draft risk evaluation prior to publishing a final risk evaluation.";

(4) by amending subsection (c) to read as follows:

"(c) PROMULGATION OF SUBSECTION (a) RULES.—

"(1) DEADLINES.—If the Administrator determines that a chemical substance presents an unreasonable risk of injury to health or the environment

Commented [A27]: ensuring that conforming changes strike para (3) and (4) of existing TSCA – we know your conforming changes are at the end.

in accordance with subsection (b)(4)(A), the Administrator—

"(A) shall propose and publish in the Federal Register a rule under subsection (a) for the chemical substance not later than 1 year after the date on which the final risk evaluation regarding the chemical substance is published;

"(B) shall publish in the Federal Register a final rule not later than 2 years after the date on which the final risk evaluation regarding the chemical substance is published; and

"(C) may extend the deadlines under this paragraph for not more than two years, subject to the condition that the aggregate length of extensions under this subparagraph and subsection (b)(4)(G)(ii) does not exceed two years, and subject to the limitation that the Adminis-

Commented [A28]: EPA TA: Edit responsive to EPA TA

trator may not extend a deadline for the publication of a proposed or final rule regarding a chemical substance drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments or a chemical substance that, with respect to persistence and bioaccumulation, scores high for 1 and either high or moderate for the other, pursuant to the TSCA Work Plan

Chemicals Methods Document published by the Administrator in February 2012 (or a successor scoring system), without adequate public justification that demonstrates, following a review of the information reasonably available to the Administrator, that the Administrator cannot complete the proposed or final rule without additional information regarding the chemical substance.

"(2) REQUIREMENTS FOR RULE.—

"(A) STATEMENT OF EFFECTS.—In promulgatingproposing and promulgating a rule under subsection sub-section (a) with respect to a chemical substance or mixture, the Administrator shall consider and publish a statement based on reasonably available infor-mationinformation with respect to—

Commented [A29]: EPA TA: Responsive to prior EPA TA, to align with the later requirement to consider the costs and benefits of the rule, both at the proposal and the final stage.

"(i) the effects of the chemical substance or mixture on health and the magnitude of the exposure of human beings to the chemical substance or mixture;

"(ii) the effects of the chemical substance or mixture on the environment and the magnitude of the exposure of the environment to such substance or mixture;

"(iii) the benefits of the chemical substance or mixture for various uses; and

"(iv) the reasonably ascertainable economic consequences of the rule, ~~after consideration~~ including consideration of—

"(I) the likely effect of the rule on the national economy, small business, technological innovation, the environment, and public health; ~~and~~

"(II) the quantifiable and nonquantifiable costs and benefits of the proposed and final regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator; and

"(III) the cost-effectiveness of the proposed regulatory action and of

Commented [A30]: EPA TA: This reverts to current TSCA 6(c), but the structure of current TSCA 6(c) is problematic as a framework to fit in all the issues that follow. For example, effects on the environment and public health are not themselves economic consequences. Also as described below, alternatives analyses are not really analyses of the effects of the actual rule. They are analyses of the effects of the alternative to the rule.

Commented [A31]: EPA TA: Slight modification of earlier TA: This new formulation is different from current sec 6(c), which says "after consideration of". Bottom line is the same though, which is that "after consideration of" seems more accurate, since not all of the considerations are economic.

Commented [A32]: EPA TA: The costs and benefits of alternatives considered do not seem relevant to the reasonably ascertainable economic consequences of the rule. These are the rules that didn't get implemented … how can they affect the cost of the rule that did get implemented?

the 1 or more primary alternative regureg-

latoryulatory actions considered by the Ad-

ministrator.

"(B) SELECTING REQUIREMENTS.—In dese-

eiding which requirements to imposelecting among prohibitions and other restric-

tions, the Administrator shall factor in the rulecon-

promulgated in accordance with subsection (a), the Administrator shall take into consideration, to the extent practicable, the considerations

siderations under subparagraph (A).

"(C) REPLACEMENT PARTS.—The Admin-

istrator "(i) IN GENERAL.—For complex dura-

ble goods and complex consumer goods, the Administrator shall exempt replacement

parts ode-

signedthat are designed prior to the effective date of the rule

for articles that are first manufactured prior to

Commented [A33]: EPA TA: Same comment as above, except with respect to cost-effectiveness.

Commented [A34]: Earlier TA: It's not clear how EPA would make the findings in i and ii during the course of a rulemaking, because it is not clear how EPA will know what articles might contain the chemical in order to made the assessment. EPA could ask for such information in comments, but that would likely yield additional information that would require another round of notice and comment.

~~the effective date of~~ publication in the ~~Federal~~ Register of the ~~Register of the~~ rule under subsection (a), unless ~~the Ad-~~ ~~"(i) the Administrator~~ ministrator finds that such ~~re-~~ replacement ~~placement~~ parts contribute significantly to the risk ~~the~~ identified in a risk ~~, including evaluation~~ conducted under subsection (b) for the chemical substance or for a chemical substance contained in a mixture to the general population or to an identified ~~risk~~ ~~to~~ potentially ~~exposed~~ ~~ex-~~ posed or susceptible ~~sub-~~ subpopulation. ~~populations; or~~

"(ii) DEFINITIONS.—In this subparagraph—

Commented [A35]: EPA TA: the articles provision below cites to (b)(4)(A) specifically

Commented [A36]: EPA TA: This formulation differs from the language in the articles provision. In addition, suggest dropping the reference to chemical substance contained in a mixture. That formulation is not generally used in the bill, and the risk assessment will be for the chemical substance and will contain whatever conclusions it contains, including with respect to mixtures.

"(I) the ~~replacement part is a compo-~~ term 'complex consumer

~~nent~~ goods' means electronic or mechanical devices composed of 50 manufactured components, with an ~~article that is reasonably ex-~~ intended useful ~~pected to be used by children aged 12~~ life of 3 or more years ~~of age~~, where the product is typically not consumed, destroyed, or discarded after a single use, and ~~younger~~ the components of which would be impracticable to redesign or replace; and

"(II) the term 'complex durable goods' means manufactured goods composed of 100 or more manufactured components, with an intended useful life of 5 or more years, where the product is typically not consumed, destroyed, or discarded after a single use.

"(D) ARTICLES.—In selecting among prohibitions and other restrictions, the Administrator shall apply such prohibitions or other restrictions to an article or category of articles containing the chemical substance or mixture

Commented [A37]: EPA TA: Should be 50 or more

Commented [A38]: EPA TA: Is there some reason this is in I but not II?

Commented [A39]: Earlier TA: (B) starts: "In deciding which requirements to impose in the rule promulgated in accordance with subsection (a)". Should use consistent phrasing throughout.

only to the extent necessary to address the identified risks from exposure to the chemical

substance or mixture from the article or category of articles, so that the substance or mixture does not present an unreasonable risk of injury to health or the environment identified in the risk evaluation conducted in accordance with subsection (b)(4)(A).

"(3) PROCEDURES.—When prescribing a rule under subsection (a) the Administrator shall proceed

in accordance with section 553 of title 5, United States Code (without regard to any reference in such section to sections 556 and 557 of such title), and shall also—

"(A) publish a notice of proposed rule-making stating with particularity the reason for the proposed rule;

"(B) allow interested persons to submit written data, views, and arguments, and make all such submissions publicly available;

"(C) promulgate a final rule based on the matter in the rulemaking record; and

"(D) make and publish with the rule the determination described in subsection (a).";

"(4) APPLICATION.—Paragraphs (1), (2), and (3) of this(5) by amending subsection apply(d) to the promulgation—ofread as follows:

Commented [A40]: EPA TA: Deletion of paragraph (4) was responsive to prior EPA TA.

"(d) EFFECTIVE DATE.—

''(1) IN GENERAL.—In any rule repealing, or making a substantive amend-

ment to, a rule promulgated under subsection (a),'';

(5) in subsection (d)—

(A) in paragraph (1), by striking ''sub-

section (a) the date'' and all that follows Administrator shall—

through ''as feasible'' and inserting ''subsection

(a)—

''(A) specify the date on which it shall take

effect; and

"~~(B) dates by~~, which date shall be as soon as prac-
ticable;
"(B) except as provided in subparagraph
~~3~~(C), specify mandatory compliance ~~is mandatory~~ dates for all
of the requirements under a rule under sub-
~~1~~section (a) which~~—~~
"~~(i)~~ shall be as soon as ~~practicable~~ prac-
~~2~~ticable, but not
~~4~~later than ~~45~~ years after the date ~~of promulga-~~
~~5~~tion of promulgation of the rule, except in a case of ~~a use ex-~~
~~6~~empted a use exempted under subsection (g);
~~"(ii)~~"(C) specify mandatory compliance dates
for the start of ban or phase-out requirements
under a rule under subsection (a), which shall
be as soon as practicable, but not later than 5
years after the date of promulgation of the rule,
except in the case of a use exempted under sub-
section (g);
"(D) specify mandatory compliance dates
for full implementation of ban or phase-out re-
quirements under a rule under subsection (a),
which shall be as soon as practicable; and
~~7~~"(E) provide for a reasonable ~~transi-~~ transition

~~tion period, including for restrictions that impose a ban or phase-out of the chemical substance;~~

~~"(iii) a period~~

Commented [A41]: **EPA TA:** In TA discussions of April 11, this was: "provide for a reasonable transition period, **subject to the compliance dates in subparagraphs (B), (C), and (D)"**

"(2) VARIABILITY.—As determined by the Administrator, the Administrator compliance dates established under paragraph (1) may vary for different affected persons; and per-

~~"(iv) following a determination by the Administrator that compliance is technologically or economically infeasible within the timeframe specified in clause (i), shall provide up to an additional 18 months for compliance to be mandatory~~sons.";~~ and~~

~~(B) in paragraph (2)—~~

~~(i) in subparagraph (A)(i)(I), by inserting ", without consideration of costs or other nonrisk factors" after "such effective date"; and~~

~~(ii) in subparagraph (B)—~~

~~(I) by striking "provide reasonable opportunity, in accordance with paragraphs (2) and (3) of subsection (c), for a hearing on such rule," and inserting "in accordance with paragraph (3) of subsection (c),"; and~~

~~(II) by striking "; and if such a hearing" and all that follows through "or revoke it";~~

(6) in subsection (e)(4), by striking "paragraphs (2), (3), and (4)" and inserting "paragraph (3)"; and

Commented [A42]: EPA TA: TSCA section 6(d)(2), providing authority to declare proposed rules effective, seems to have been stricken. Was the intended?

(7) by adding at the end the following new subsections:

"(g) EXEMPTIONS.—

"(1) CRITERIA FOR EXEMPTION.—The Administrator may, as part of a rule promulgated under subsection (a), or in a separate rule, grant an exemption from a requirement of a subsection (a) rule for a specific use of a chemical substance or mixture, if the Administrator finds that—

"(A) the specific use is a critical or essential use for which no technically and economically feasible safer alternative is available, taking into consideration hazard and exposure;

"(B) compliance with the requirement, as applied with respect to the specific use, would significantly disrupt the national economy, national security, or critical infrastructure; or

"(C) the use of the chemical substance or mixture, as compared to reasonably available alternatives, provides a substantial benefit to health, the environment, or public safety.

"(2) EXEMPTION ANALYSIS AND STATEMENT.—In proposing an exemption under this subsection, the Administrator shall analyze the need for the exemption, and shall make public the analysis and a statement describing how the analysis was taken into account.

~~"(3) ANALYSIS IN CASE OF BAN OR PHASE-OUT.—In determining whether an exemption should be granted for a chemical substance for which a ban or phase-out is proposed, the Administrator shall take into consideration, to the extent practicable based on reasonably available information, the quantifiable and nonquantifiable costs and benefits of the 1 or more alternatives to the chemical substance the Administrator determines to be technically and economically feasible and most likely to be used in place~~

of the chemical substance under the conditions of use.

"(4) PERIOD OF EXEMPTION.—The Administrator shall establish, as part of a rule under this subsection, a time limit on any exemption for a time to be determined by the Administrator as reasonable on a case-by-case basis, and, by rule, may extend, modify, or eliminate an exemption if the Administrator determines, on the basis of reasonably available information and after adequate public justification, the exemption warrants extension or modification or is no longer necessary.

"(5) CONDITIONS.—As part of a rule promulgated under this subsection, the Administrator shall include conditions, including reasonable record-keeping, monitoring, and reporting requirements, to the extent that the Administrator determines the

conditions are necessary to protect health and the environment while achieving the purposes of the exemption.

"(h) CHEMICALS THAT ARE PERSISTENT, BIOACCUMULATIVE, AND TOXIC.—~~For a chemical substance subject to~~ "(1) EXPEDITED ACTION.—Not later than 3 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall propose rules under subsection (a) ~~that~~ with respect to chemical substances identified in the 2014 update of the TSCA Work Plan for Chemical Assessments—

"(A) that the Administrator has a reasonable basis to conclude are toxic and that with respect to persistence and bioaccumulation, ~~scores~~ score high for ~~1~~ one and either high or moderate for the other, pursuant to the TSCA Work Plan

Commented [A43]: Earlier TA: This could cause confusion about what the unreasonable risk standard is under the bill. This suggests that it's something other than what's necessary to protect health and the environment. Would be better if provision allowed EPA to impose conditions "to protect health and the environment to the extent practicable while achieving..." or something like that.

Chemicals Methods Document published by the ~~Adminis-~~ ~~trator~~Administrator in February 2012 (or a successor scoring system~~)~~), and are not a metal or a metal compound, and for which the Administrator has not completed a Work Plan Problem Formulation, initiated a review under section 5, or entered into a consent agreement under section 4, prior to the date of enactment of the Frank R.

Lautenberg Chemical Safety for the 21st Century Act; and

"(B) exposure to which under the conditions of use is likely to the general population or to a potentially exposed or susceptible subpopulation identified by the Administrator, or the environment, on the basis of an exposure and use assessment conducted by the Administrator.

"(2) NO RISK EVALUATION REQUIRED.—The Administrator shall, in not be required to conduct risk evaluations on chemical substances that are subject to paragraph (1).

"(3) FINAL RULE.—Not later than 18 months after proposing a rule pursuant to paragraph (1), the Administrator shall promulgate a final rule under subsection (a).

"(4) SELECTING RESTRICTIONS.—In selecting among prohibitions and other restrictions, promulgated in a rule under subsection (a) pursuant to paragraph (1), the Administrator shall address the risks of injury to health or the environment that the Administrator determines are presented by the chemical substance and shall reduce likely exposure to the sub-

stancesubstance to the maximum extent practicable.

"(5) RELATIONSHIP TO SUBSECTION (B).—If, at any time prior to the date that is 90 days after the date on which the Administrator proposes a rule under paragraph (1) with respect to a chemical substance, the Administrator makes a designation under subsection 6(b)(1)(B)(i), or receives a request under section 6(b)(4)(C)(ii) that meets the criteria prescribed by the Administrator in the rule promulgated under section 6(b)(4)(B), such chemical substance shall not be subject to this subsection, except that in selecting among prohibitions and other restrictions promulgated in a rule pursuant to subsection (a), the Administrator shall both ensure that the chemical substance meets the rulemaking standard under subsection (a) and reduce exposure to the substance to the extent practicable.

"(i) FINAL AGENCY ACTION.—Under this section and subject to section 18—

"(1) a determination by the Administrator that is based on a risk evaluation conducted in accordance with under subsection (b)(4)(A) that a chemical substance does not present an unreasonable risk of injury to health or the environment shall be issued by order and considered to be a final agency action, effective beginning on the date of issuance of the

Commented [A44]: EPA TA: Change responsive to prior EPA TA.

925 order; and

"(2) a final rule promulgated under subsection (a), and the associated determination by the Administrator that is based on a risk evaluation conducted in accordance with subsection (b)(4)(A) on the basis of that a chemical substance presents an unreasonable risk of injury to health or the environment shall be considered to be a final agency action, effective beginning on the date of promulgation of the final rule.

Commented [A45]: EPA TA: EPA previously flagged the "based on" formulation as potentially supporting an argument that the unreasonable risk determination follows from and is separate from the risk evaluation (and could therefore include cost considerations).

Especially since that issue has been addressed in the paragraph above, a conforming edit should be made here.

We suggest "determination by the Administrator under subsection (b)(4)(A) that a chemical substance presents ... "

"(j) CHEMICAL SUBSTANCES CURRENTLY ASSESSED AS LOW-HAZARD.—Not later than one year after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall publish a list of not fewer than 25 chemical substances, including uses of a chemical substance identified by the Administrator, that the Administrator has reason to conclude should not be high priorities for risk evaluation under this section because information demonstrates that such chemical substances do not pose a hazard to human health or the environment.

"(k) DEFINITION.—For the purposes of this Act, the term 'requirement' as used in this section shall not displace statutory or common law.".

(b) TABLE OF CONTENTS AMENDMENT.—The item in the table of contents of such Act relating to section 26 is amended to read as follows:

Commented [A46]: EPA TA: EPA notes three issues with this passage:

1) The title says low hazard but the text establishes that the true criterion is no hazard. This may lead to problematic confusion when it is time to implement.

2) EPA doubts that any chemical substance would meet the "do[es] not pose a hazard" standard.

3) No fees are available to defray the cost of responding to industry claims that particular chemical substances are low hazard or no hazard.

"Sec. 5. Prioritization, risk evaluation, and regulation of chemical substances and mixtures.".

Commented [A47]: Not section 6?

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/11/2016 6:38:04 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TA request on PBTs (Conf Proposal)
Attachments: Markey.TSCA TA.PBT (Conf Proposal).docx

Michal,
This TA responds to the request on PBTs.

We see a number of unresolved issues in this draft (see attached comments).

In response to your question about how many PBT chemical substances would likely be captured by this language if it were not limited to chemical substances already on the EPA Workplan, EPA does not have an exact answer. However, a 2013 rescoring of just 345 chemicals – a small subset of TSCA inventory – revealed 41 chemicals (23 non-Workplan and 18 Workplan chemicals) that would meet the bill's high-high/moderate criteria for P and B. (Note that some of these chemicals are metals, and therefore excluded from the risk management requirements). Application of the bill's criteria to the full TSCA Inventory is likely to yield an even higher number of identified PBT chemicals, and a significant increase in EPA's risk management workload.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>
Date: April 11, 2016 at 6:56:33 AM EDT
To: "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov>
Subject: Re: Sen. Markey TSCA TA request on PBTs 04-09-16PBT (Conf Proposal)

Quick followup

The House bill has a 9 month process for epa to identify high pbts. Did EPA ever provide TA or consider what that process would result in? Are there many more high PBTS out there that are not on the workplan?

Thx
M

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

From: Kaiser, Sven-Erik
Sent: Sunday, April 10, 2016 2:48 PM
To: Freedhoff, Michal (Markey)
Subject: Re: Sen. Markey TSCA TA request on PBTs 04-09-16PBT (Conf Proposal)

Michal,
Thanks for the draft- checking on the question. Best,
Sven

On Apr 10, 2016, at 2:46 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Thanks. new draft attached. pls take a look to see if earlier qs answered.

IN your view, what is the difference between "likely exposure" and "exposure" – both were used in this draft and I have made them all "likely" for now.

Thanks
m

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey
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From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Sunday, April 10, 2016 1:39 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA request on PBTs 04-09-16PBT (Conf Proposal)

Michal- see attached TA requested on PBTs.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any questions. Thanks,
Sven

From: "Freedhoff, Michal (Markey)" <Michal_Freedhoff@

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To: "Sven-ErikKaiser(Kai_ser_.Sven-Erik@epamail_.epa_

gov)" <Kaiser.Sven-Erik@epamail.epa.gov>
Subject: 04

-09-16PBT(ConfProposal).docx

Sven

Could you please

review paragraphs 1-3 of this document to

make sure it does what

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This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy position of the agency and the administration on the bill, the draft language and the comments.

( ) Chemicals That Are Persistent, Bioaccumulative, and Toxic.--

(1) Expedited Action.--Not later than 2 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall propose a rule under subsection (a) with respect to chemical substances identified in the 2014 update of the TSCA Work Plan for Chemical Assessments —

(A) that the Administrator has a reasonable basis to conclude are toxic and with respect to persistence and bioaccumulation, scores high for one and either high or moderate for the other, pursuant to the TSCA Work Plan Chemicals Methods Document published by the Administrator in February 2012 (or a successor scoring system), and are not a metal or a metal compound, and for which the Administrator has not completed a Work Plan Problem Formulation under section 6, initiated a risk assessment under section 5, or entered into a consent agreement under section 4 prior to the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act; and

Commented [A1]: Question for DK: no fees for these I assume based on current 26?

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Commented [A2]: **EPA TA:** Unresolved issue. Per earlier TA to House, there is some awkwardness in proceeding directly to the risk management rule without having made the negative safety determination. Per comments below, it's not clear if the intent is that EPA meet that (a) standard AND reduce exposure as practicable for these PBTs, or just reduce exposure to extent practicable. That should be clarified. If it's the former, then there could be some awkwardness in being directed to eliminate an unreasonable risk that EPA has not found exists.

Commented [A3]: **EPA TA:** Unresolved issue. Note that, because these chemical go directly to rulemaking without risk evaluation, the rulemaking work will not be covered by fees, if the fee trigger is for chemical subject to risk evaluation.

Commented [A4]: **EPA TA:** Unresolved TA. This will be a challenging deadline to meet for the 9 or so chemicals that would be subject to it.

Commented [A5]: **EPA TA:** Unresolved Issue. Under current TSCA, EPA does not complete Work Plan Problem Formulations "under section 6." Section 6 of current TSCA does not specifically direct or authorize these. They are just a part of EPA's work practices.

We suggest deleting "under section 6."

Commented [A6]: **EPA TA:** Unresolved Issue. Under current TSCA, EPA does reviews "under section 5," but not full risk assessments.

We suggest replacing "risk assessment" with "review."

Commented [A7]: To EPA: The original terms were derived from your earlier TA to me on the 3 PBTS we are trying to exclude, not from anything we are working on in sections 5 and 6. Does this work?.

Commented [A8R7]: **EPA TA:** No it does not work. See TA below.

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(B) exposure to which under the conditions of use is likely to the general population or to a potentially exposed or susceptible subpopulation identified by the Administrator, on the basis of an exposure and use assessment conducted by the Administrator.

(2) Final Rule.--Notwithstanding subsection (__), ~~subject to the availability of appropriations~~ and subsections __ and __ , not later than 2 years after proposing a rule under paragraph (1), the Administrator shall promulgate a rule under subsection (a) with respect to each chemical substance for which a rule is proposed under paragraph (1) to reduce likely exposure to the extent practicable.

(3) Relationship to subsection (b).--If, at any time prior to the date that is 90 days after the date on which the Administrator proposes the rule under paragraph (1), the Administrator makes a finding under subsection (__), or a manufacturer requests a risk evaluation under subsection (__), with respect to a chemical substance, such chemical substance shall not be

Commented [A9]: EPA TA: Unresolved Issue. Do you intend to exclude environmental exposure as a trigger?

Commented [A10]: What does this entail and how long does it take?

Commented [A11R10]: EPA TA: Generally, for a use and exposure assessment, EPA would need to do research to identify uses and use scenarios, then estimate routes, duration, extent of exposure, etc. for those various use scenarios, as well as the nature and number of individuals exposed and the dose they may receive both acutely and chronically. We also look at environmental release and environmental fate and transport. This often involves complex modeling to estimate exposure in the frequent case where we do not have reliable monitoring information. This can take 12 months or longer, depending on the number of use scenarios, availability of data, etc.

Commented [A12]: X-ref to provision requiring risk management rules on the basis of a risk evaluation

Commented [A13]: Need to cross-reference language on 50% discount for Work Plans, ensure numerical limitation does not apply, ensure cost-benefit analysis applies to selected risk management measures, and ensure critical use and other exemptions apply.

Commented [A14]: EPA TA: Unresolved Issue. Is the following standard ("reduce likely exposure") in addition to, or instead of, the ordinary risk management standard for a rule under 6(a)?

Commented [A15]: EPA TA: We'd construe that as reduce the potential for exposure, but some might argue that "to the extent practicable" and "likely" are in tension. How far does EPA reduce the potential for exposure? As much as practicable, or just to the point where it is less than 50% likely to occur?

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subject to this subsection, except that, any proposed and final rule shall reduce likely exposure to the extent practicable.

Commented [A16]: EPA TA: Unresolved issue. This should be an "or." You want the instructions to apply to either a proposed or final rule. It would be clearest to say: "any proposed or final rule for such chemical substance shall . . ."

Commented [A17]: EPA TA: Unresolved issue. . . Is the following standard ("reduce likely exposure") in addition to, or instead of, the ordinary risk management standard for a rule under 6(a)?

(4) OTHER CHEMICALS THAT ARE PERSISTENT, BIOACCUMULATIVE, AND TOXIC OR CARCINOGENS.—

(A) In designating high priority substances pursuant to subsection (b), the Administrator shall give preference to—

(i) chemical substances that, with respect to persistence and bioaccumulation, score high for 1 and either high or moderate for the other, pursuant to the TSCA Work Plan Chemicals Methods Document published by the Administrator in February 2012 (or a successor scoring system); and

(ii) chemical substances listed in the 2014 update of the TSCA Work Plan for Chemical Assessments that are known human carcinogens and have high acute and chronic toxicity.

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(B) In identifying priorities for risk evaluation and conducting risk evaluations of metals and metal compounds, the Administrator shall use the Framework for Metals Risk Assessment of the Office of the Science Advisor, Risk Assessment Forum, and dated March 2007 (or a successor document), and may use other applicable information consistent with the best available science.

(C) For a chemical substance subject to subsection (a) and with respect to persistence and bioaccumulation, scores high for 1 and either high or moderate for the other, pursuant to the TSCA Work Plan Chemicals Methods Document published by the Administrator in February 2012 (or a successor scoring system) the Administrator shall, in selecting among prohibitions and other restrictions promulgated in a rule pursuant to subsection (c), reduce exposure to the substance to the extent practicable.

Commented [A18]: EPA TA: Unresolved issue. It would be clearer if "and" were changed to "that."

Commented [A19]: EPA TA: Unresolved issue. Why is this here, but omitted above when discussing reduction to the extent practicable?

Retain expedited action provision in 6(c)

(G) may extend the deadlines under this paragraph for not more than two years, subject to the condition that the aggregate length of extensions under this paragraph and subsection (b)(4)(G) does not exceed two years, and subject to the limitation that the Administrator may not extend a

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deadline for the publication of a proposed or final rule regarding a chemical substance drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments or a chemical substance that, with respect to persistence and bioaccumulation, scores high for 1 and either high or moderate for the other, pursuant to the TSCA Work Plan Chemicals Methods Document published by the Administrator in February 2012 (or a successor scoring system), without adequate public justification that demonstrates, following a review of the information reasonably available to the Administrator, that the Administrator cannot complete the proposed or final rule without additional information regarding the chemical substance.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/17/2016 4:38:10 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: RE: Sen. Markey TSCA TA Followup Request on CBI - health and safety studies

Got it -thanks

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Thursday, March 17, 2016 12:27 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Markey TSCA TA Followup Request on CBI - health and safety studies

Another formulation

> (1) BAN OR PHASE-OUT .—(A) If the Administrator promulgates a rule pursuant to section 6(a) that establishes a ban or phase-out of a chemical substance, the protection from disclosure of any information under this section with respect to the chemical substance shall be presumed to no longer apply, subject to a review of a request to maintain protections under subsections (g)(1) (g)(2) and (g)(3).

Michal Ilana Freedhoff, Ph.D.
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255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

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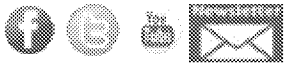

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Wednesday, March 16, 2016 7:00 PM
To: Freedhoff, Michal (Markey)
Subject: Re: Sen. Markey TSCA TA Followup Request on CBI - health and safety studies

Got it-checking along with the last one. Thanks,
Sven

On Mar 16, 2016, at 6:46 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Does this work for 14(c)(3)(B)

(B) EXCEPTIONS FROM PRESUMPTION

(i) Paragraph (3)(A) shall not apply to any condition of use of a chemical substance for which an exemption under section 6(g) has been granted;

(ii) For a ban or phase-out of a chemical substance that is not established for all conditions of use of the chemical substance, paragraph (3)(A) shall apply only to information about the chemical substance that relates solely to the conditions of use for which the ban or phase-out is established ;

(iii) Paragraph (3)(A) shall apply to a chemical substance for which a ban or phase-out has been established if the chemical substance continues to be manufactured, processed and distributed solely for export if EPA determines that section 12(a)(1) shall not apply to the chemical substance in accordance with section 12(a)(2). [MF1] ; and

(iv) Paragraph (3)(A) shall apply to a chemical substance that is subject to a phase out at such time as the phase out is fully implemented.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

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From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Tuesday, March 15, 2016 4:43 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA Followup Request on CBI - health and safety studies

Michal – please see the requested followup TA on CBI and health and safety studies.

Here is an excerpt of current senate 14 with some highlighted text, the first of which was not in the Senate-passed bill. In your opinion does this first portion of highlighted text change a) existing EPA practice and b) meaning compared to Senate-passed text. I'm not reading your response below as a "yes" to either question but I want to be sure.

Response: EPA would interpret the highlighted language to effect no changes in either EPA practice or the Senate passed bill. EPA has always addressed the mix of CBI and non-CBI information in a particular document, assessing what needs to be protected and what does not, which is what the second highlighted text appears to require.

That said, others may argue that the *new* highlighted text does effectuate a change in both the bill and practice. EPA would not interpret (c)(2) as a condition or limitation on (c)(1), because it merely provides that information that is protectable remains protectable even if mixed with non-protectable information, a position EPA already takes. However, the new highlighted text might be argued to indicate that (c)(2) in some way limits or conditions the scope of information releasable pursuant to (c)(1).

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA

Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, March 15, 2016 1:16 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Markey TSCA TA Request on CBI - health and safety studies

Here is an excerpt of current senate 14 with some highlighted text, the first of which was not in the Senate-passed bill. In your opinion does this first portion of highlighted text change a) existing EPA practice and b) meaning compared to Senate-passed text. I'm not reading your response below as a "yes" to either question but I want to be sure.

(c) Information Not Protected From Disclosure.—

(1) IN GENERAL.—Notwithstanding subsections (a) and (b), and subject to paragraph (2), the following information shall not be protected from disclosure:

(A) INFORMATION FROM HEALTH AND SAFETY STUDIES.—

(i) IN GENERAL.—Subject to clause (ii)—

(I) any health and safety study that is submitted under this Act with respect to—

(aa) any chemical substance or mixture that, on the date on which the study is to be disclosed, has been offered for commercial distribution; or

(bb) any chemical substance or mixture for which—

(AA) testing is required under section 4; or

(BB) a notification is required under section 5; or

(II) any information reported to, or otherwise obtained by, the Administrator from a health and safety study relating to a chemical substance or mixture described in item (aa) or (bb) of subclause (I).

(ii) EFFECT OF SUBPARAGRAPH.—Nothing in this subparagraph authorizes the release of any information that discloses—

(I) a process used in the manufacturing or processing of a chemical substance or mixture; or

(II) in the case of a mixture, the portion of the mixture comprised by any chemical substance in the mixture.

(B) OTHER INFORMATION NOT PROTECTED FROM DISCLOSURE.—The following information is not protected from disclosure under this section:

(i) For information submitted after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the specific identity of a chemical substance as of the date on which the chemical substance is first offered for commercial distribution, if the person submitting the information does not meet the requirements of subsection (d).

(ii) A safety assessment developed, or a safety determination made, under section 6.

(iii) Any general information describing the manufacturing volumes, expressed as specific aggregated volumes or, if the Administrator determines that disclosure of specific aggregated volumes would reveal confidential information, expressed in ranges.

(iv) A general description of a process used in the manufacture or processing and industrial, commercial, or consumer functions and uses of a chemical substance, mixture, or article containing a chemical substance or mixture, including information specific to an industry or industry sector that customarily would be shared with the general public or within an industry or industry sector.

(2) MIXED CONFIDENTIAL AND NONCONFIDENTIAL INFORMATION.—Any information that is eligible for protection under this section and is submitted with information described in this subsection shall be protected from disclosure, if the submitter complies with subsection (d), subject to the condition that information in the submission that is not eligible for protection against disclosure shall be disclosed.

Michal Ilana Freedhoff, Ph.D.
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Office of Senator Edward J. Markey

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Washington, DC 20510
202-224-2742

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From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Tuesday, March 15, 2016 1:13 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA Request on CBI - health and safety studies

Michal,
This responds to your TA request on CBI and health and safety studies.

Question: Currently if there is CBI in a health and safety study that is not the chemID sort that existing tsca protects, does EPA redact that CBI prior to releasing the health and safety study?

EPA Response: The companies provide a sanitized version of the submission which is what we publish, assuming no final determination has been made regarding eligibility for confidential treatment.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, March 15, 2016 10:32 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: TA - health and safety studies

Sven

Currently if there is CBI in a health and safety study that is not the chemID sort that existing tsca protects, does EPA redact that CBI prior to releasing the health and safety study?

Thx
M

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/2/2016 10:49:05 PM
To: Foster, Lakecia (Durbin) [Lakecia_Foster@durbin.senate.gov]
Subject: Re: Sen. Durbin TA Request on draft Lead-Safe Housing for Kids Act

Kecia,
Thanks for the follow up inquiry. In response to your questions, we didn't think it was necessary to repeat the discussion from the call. Also the TA suggests a health based standard would be an alternative. We hurried the TA to meet your deadline of COB today, please let me know if you would like additional TA and the deadline. Thanks,
Sven

On Mar 2, 2016, at 5:19 PM, Foster, Lakecia (Durbin) <Lakecia_Foster@durbin.senate.gov> wrote:

Sven- Thanks for the feedback. However, there is no mention of the lead-based paint standards we discussed this afternoon. Am I missing something? Are there suggestions on what the appropriate standard should be if "best available science" is not appropriate?

Lakecia Foster
Economic Policy Advisor
U.S. Senator Richard J. Durbin
Assistant Democratic Leader
711 Hart Senate Office Building
202-224-2152

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Wednesday, March 02, 2016 5:16 PM
To: Foster, Lakecia (Durbin) <Lakecia_Foster@durbin.senate.gov>
Subject: Sen. Durbin TA Request on draft Lead-Safe Housing for Kids Act

Kecia,
This responds to your technical assistance request on the draft lead paint bill.

Page 1, line 24-25: the term "in accordance with the best available science" is unclear as to what criteria EPA should use to update, e.g., health based?

Page 2, line 25-26: "require a risk assessment for all housing receiving Federal assistance" A risk assessment reflects current conditions only. Lead paint is not static; a hazardous condition could emerge the day after a clean risk assessment. Note that without regular (e.g., annual) followup checks, this is unlikely to result in reliable risk reduction.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Foster, Lakecia (Durbin) [mailto:Lakecia_Foster@durbin.senate.gov]
Sent: Wednesday, March 02, 2016 1:40 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Durbin Inquiry on lead-contaminated hazards

Sven- thanks for arranging the call. Here's the latest draft from leg counsel. It does not include the changes HUD made to this draft, which I am working on incorporating. The EPA section is under Sec. 3 and a reference in the GAO report. However, it does not include amending the lead-based paint definition. We were thinking of adding lead-contaminated paint under Section 3 with the other standards, but that may not be the way to go.

It would be helpful to get TA on directing the standard to be evaluated to see if should be updated based on the best available science.

If I could be get something before COB today, that would be great. Working on a tight timeline.

Thanks,
Kecia

Lakecia Foster
Economic Policy Advisor
U.S. Senator Richard J. Durbin
Assistant Democratic Leader
711 Hart Senate Office Building
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From: Foster, Lakecia (Durbin)
Sent: Wednesday, March 02, 2016 10:07 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Durbin Inquiry on lead-contaminated hazards

Great. Thanks!

Lakecia Foster
Economic Policy Advisor
U.S. Senator Richard J. Durbin
Assistant Democratic Leader
711 Hart Senate Office Building
202-224-2152

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Wednesday, March 02, 2016 10:06 AM
To: Foster, Lakecia (Durbin) <Lakecia_Foster@durbin.senate.gov>
Subject: Re: Sen. Durbin Inquiry on lead-contaminated hazards

Kecia- let's have a call at 1pm. Please call 866-299-3188, code 202-566-2753#. Please let me know if any questions.
Thanks,
Sven

On Mar 2, 2016, at 9:57 AM, Foster, Lakecia (Durbin) <Lakecia_Foster@durbin.senate.gov> wrote:

Sven- Yes! I'm available between 10-11 am and between 11:30-1:30. If these time's don't work, I can find another time.

Thanks for your quick turnaround on this.

Lakecia Foster
Economic Policy Advisor
U.S. Senator Richard J. Durbin
Assistant Democratic Leader
711 Hart Senate Office Building
202-224-2152

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Wednesday, March 02, 2016 9:51 AM
To: Foster, Lakecia (Durbin) <Lakecia_Foster@durbin.senate.gov>
Subject: RE: Sen. Durbin Inquiry on lead-contaminated hazards

Kecia – in response to your TA request on lead-based paint - any time available today for a quick phone call to discuss? We use different terms than the ones you indicate and I want to loop in key program folks to answer your questions. Thanks,
Sven

Sven-Erik Kaiser
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From: Foster, Lakecia (Durbin) [mailto:Lakecia_Foster@durbin.senate.gov]
Sent: Tuesday, March 01, 2016 5:54 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Durbin Inquiry on lead-contaminated hazards

Thanks.

We have some advocates that are interested in aligning the CPSC definition of lead-based paint with the one under the Lead-Based Paint Poisoning Prevention Act. I would like to know the difference in the definitions and why they are differ. I also would like to know what would be the impact of changing to the lower standard. Also, is there a difference between the definition and EPA's regulations on lead-contaminated paint?

We are finalizing text tomorrow for introduction on Thursday. Sorry for the late notice, but it is an issue that came up on my call with HUD today.

Thanks,
Kecia

Lakecia Foster
Economic Policy Advisor
U.S. Senator Richard J. Durbin
Assistant Democratic Leader
711 Hart Senate Office Building

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From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Tuesday, March 01, 2016 3:44 PM
To: Foster, Lakecia (Durbin) <Lakecia_Foster@durbin.senate.gov>
Subject: Sen. Durbin Inquiry on lead-contaminated hazards

Lakecia,
Thanks for the inquiry about lead based paint hazards. Please let me know your questions and I'll be glad to provide a response or set up a call with our lead folks. Best,
Sven

Sven-Erik Kaiser
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202-566-2753

From: Foster, Lakecia (Durbin) [mailto:Lakecia_Foster@durbin.senate.gov]
Sent: Tuesday, March 01, 2016 2:30 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: EPA lead-contaminated hazards

Hi Sven,

My colleague, Jasmine Hunt, forwarded your contact information to me. I'm working on a bill regarding HUD lead regulations. We are also including related provisions that under EPA's jurisdiction. Do you have a moment to chat about the lead-based paint definition and EPA's regulations on lead-contaminated paint?

Thanks,
Kecia

Lakecia Foster
Economic Policy Advisor
U.S. Senator Richard J. Durbin
Assistant Democratic Leader
711 Hart Senate Office Building
202-224-2152

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/24/2016 2:14:16 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TA on House section 6 (4-22) - 6(i) issue
Attachments: Markey.TSCA TA.Conforming Changes for 6(i).docx

Michal,
The attached TA responds to the request on section 6(i) conforming changes raised by HLC.

Attached are our thoughts about the inclusion of reference to 6(i) orders in the sections identified. The questions largely appear to arise from the view that a section 6(i) order is something different from or more than the determination that a chemical substance does not present an unreasonable risk. As we interpret the language, Congress is merely specifying that EPA's determination is an order; it does not require EPA to issue a separate order. We believe this would be true under the APA anyway, which defines "order" as "a final disposition, whether affirmative, negative, injunctive, or declaratory in form, of any agency in a matter other than a rule making. . . ." (sec 551(6)).

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
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202-566-2753

> **From:** "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>
> **Date:** April 23, 2016 at 9:22:05 PM EDT
> **To:** "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov>
> **Subject: Re: Sen. Markey TSCA TA on House section 6 (4-22)**
> In conforming changes at back there are a number of places where hlc wants to know if we shd add 6(i) orders to a list of orders now covered by various sections. In some places we think yes and in others no. If you guys have a view let me know. Thx.
>
> Michal Ilana Freedhoff, Ph.D.
> Director of Oversight and Investigations
> Office of Senator Edward J. Markey (D-MA)

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/15/2016 7:23:01 PM
To: Michal_Freedhoff@markey.senate.gov
Subject: Fwd: Sen. Markey TSCA TA request on Jackie's 6
Attachments: Markey TSCA TA Updated Table on Cost Considerations, 4.15.16.docx; ATT00001.htm

Michal - the attached TA responds to the request on Jackie's section 6 included updated cost considerations chart.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser

U.S. EPA

Office of Congressional and Intergovernmental Relations

1200 Pennsylvania Ave., NW (1305A)

Washington, DC 20460

202-566-2753

From: "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>
Date: April 15, 2016 at 10:22:25 AM EDT
To: "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov>
Subject: Fw: Jackie's 6

On section 6 pls esp look at p 10 lines 14 and on. And rank on the chart? Asap would be good.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

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1) Can you rank these in order of added analytic burden to EPA (ie analysis above what is already required under administrative law, RIA, what EPA would expect to do as part of any rulemaking analysis, etc), and describe briefly the basis for the ranking?

2) Can you rank these in order of added litigation risk that the formulations may present, and describe (briefly) the basis for the ranking?

Cost Considerations in a Rule

- **"S 697"**

"(4) ANALYSIS FOR RULEMAKING.—

"(A) CONSIDERATIONS.—In deciding which restrictions to impose under paragraph (3) as part of developing a rule under paragraph (1), the Administrator shall take into consideration, to the extent practicable based on reasonably available information, the quantifiable and nonquantifiable costs and benefits of the proposed regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator.

"(B) ALTERNATIVES.—As part of the analysis, the Administrator shall review any 1 or more technically and economically feasible alternatives to the chemical substance that the Administrator determines are relevant to the rulemaking.

"(C) PUBLIC AVAILABILITY.—In proposing a rule under paragraph (1), the Administrator shall make publicly available any analysis conducted under this paragraph.

"(D) STATEMENT REQUIRED.—In making final a rule under paragraph (1), the Administrator shall include a statement describing how the analysis considered under subparagraph (A) was taken into account.

- **"MERGED HOUSE/SENATE PROPOSAL"**

d) PROMULGATION OF SUBSECTION (b) RULES.

(1) **REQUIREMENTS FOR RULE.—**In promulgating any rule under subsection (b) with respect to a chemical substance or mixture, the Administrator shall factor in the following considerations, and publish a statement describing how they were factored into the rule—

(A) the effects of ~~such~~ **the chemical** substance or mixture on health and the magnitude of the exposure of human beings to **the chemical** ~~such~~ substance or mixture;

(B) the effects of ~~such~~ **the chemical** substance or mixture on the environment and the magnitude of the exposure of the environment to such substance or mixture~~,~~**;**

(C) the benefits of ~~such~~ **the chemical** substance or mixture for various uses; and ~~the availability of substitutes for such uses, and~~

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(D) ~~)~~ the reasonably ascertainable economic consequences of the rule, after consideration of

(i) ~~after~~ the **likely** effect ~~on~~ **of the rule on** the national economy, small business, technological innovation, the environment, and public health;~~.~~

(ii) the quantifiable and nonquantifiable costs and benefits of the proposed regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator. ;

(E) any 1 or more technically and economically feasible alternatives to the chemical substance that the Administrator determines are relevant to the rulemaking. ;

❖ **"SENATE OFFER"**

(2) REQUIREMENTS FOR RULE.—

(A) In promulgating a rule under subsection (a) with respect to a chemical substance or mixture, the Administrator shall consider and publish a statement based on reasonably available information with respect to—

(i) the effects of the chemical substance or mixture on health and the magnitude of the exposure of human beings to the chemical substance or mixture,;

(ii) the effects of the chemical substance or mixture on the environment and the magnitude of the exposure of the environment to such substance or mixture,;

(iii) the benefits of the chemical substance or mixture for various uses; and

(iv) the reasonably ascertainable economic consequences of the rule, after consideration of:

(v) the likely effect of the rule on the national economy, small business, technological innovation, the environment, and public health; and

(vi) The quantifiable and non-quantifiable costs and benefits of the proposed regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator;

(B) In deciding which requirements to impose as part of developing the rule under subsection (a), the Administrator shall take into consideration, to the extent practicable, the considerations required under subparagraph (A).

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❖ **"SUPPLEMENTED SENATE OFFER"**

(2) REQUIREMENTS FOR RULE.—

(A) In promulgating a rule under subsection (a) with respect to a chemical substance or mixture, the Administrator shall consider and publish a statement based on reasonably available information with respect to—

(i) the effects of the chemical substance or mixture on health and the magnitude of the exposure of human beings to the chemical substance or mixture,;

(ii) the effects of the chemical substance or mixture on the environment and the magnitude of the exposure of the environment to such substance or mixture,;

(iii) the benefits of the chemical substance or mixture for various uses; and

(iv) the reasonably ascertainable economic consequences of the rule, after consideration of:

(v) the likely effect of the rule on the national economy, small business, technological innovation, the environment, and public health; and

(vi) The quantifiable and non-quantifiable costs and benefits of the proposed regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator;

(B) In deciding which requirements to impose as part of developing the rule under subsection (a), the Administrator shall take into consideration, to the extent practicable, the considerations required under subparagraph (A) **and shall consider whether the proposed regulatory action and the 1 or more primary alternative regulatory actions considered by the Administrator under subparagraph (A)(vi) are cost-effective.**

❖ **"H.R. 2576 AS MODIFIED USING EPA TA"**

(B) impose requirements under the rule that the Administrator determines, to the extent practicable based on the information published under subparagraph (A), are cost-effective, except where the Administrator determines that additional or different requirements described in subsection (a) are necessary to ensure that the chemical substance no longer presents or will present an unreasonable risk, including an identified unreasonable risk to a potentially exposed population.

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- **"H.R. 2576"**

  (B) impose requirements under the rule that the Administrator determines, consistent with the information published under subparagraph (A), are cost-effective, except where the Administrator determines that additional or different requirements described in subsection (a) are necessary to protect against the identified risks.

- **SET A from EPA March 21 TA: using the term cost-effectiveness, based on Senate offer structure**

  1. Add to 6(c)(2)(A)--

     "(vii) the cost-effectiveness of the proposed regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator;"

  2. Add the above to 6(C)(2)(A) and add the following at the end of the last sentence of 6(C)(2)(B)—

     "and shall generally give preference to requirements that are more cost-effective as determined based on the consideration described in 6(c)(2)(A)(vii)"

- **SET B from EPA March 21 TA: not using the term cost-effectiveness, based on Senate offer structure**

  1. Add to 6(c)(2)(A)—

  "(vii) the efficiency with which the proposed regulatory action and the 1 or more primary alternative regulatory actions considered by the Administrator satisfy the requirement that a rule promulgated under section 6(a) ensures that the chemical substance does not present an unreasonable risk of injury to health or the environment under the conditions of use, as determined in accordance with subsection (b)(4)(A);"

  2. Add the above to 6(c)(2)(A) and add the following at the end of the last sentence of 6(c)(2)(B)—

     "and shall generally give preference to requirements that are more efficient in satisfying the requirement that a rule promulgated under section 6(a) ensures that the chemical substance does not present an unreasonable risk of injury to health or the environment under the conditions of use as determined in accordance with subsection (b)(4)(A)"

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- **SET C from EPA March 21 TA: two versions of revision to House bill language, hewing closest to that language**

  Version 1: (B) impose requirements under the rule that the Administrator determines, to the extent practicable based on the information published under subparagraph (A), are cost-effective, except where the Administrator determines that requirements described in subsection (a) that are in addition to or different from the cost-effective requirements the Administrator was able to identify during the rulemaking process are necessary to ensure that the chemical substance no longer presents or will present an unreasonable risk of injury to health or the environment under the intended conditions of use, including an identified unreasonable risk to a potentially exposed population.

  Version 2: (B) impose requirements under the rule that the Administrator determines, to the extent practicable based on the information published under subparagraph (A), are more cost-effective than the other requirements considered by the Administrator, except where the Administrator determines that one or more of the other requirements are necessary to ensure that the chemical substance no longer presents or will present an unreasonable risk of injury to health or the environment under the intended conditions of use, including an identified unreasonable risk to a potentially exposed population.

- **SET D from EPA March 21 TA: more substantial revision to House bill language, to establish a preference rather than a presumption**

  (B) generally give preference to requirements that the Administrator determines, to the extent practicable based on the information published under subparagraph (A), are more cost-effective.

- **APRIL 8 sent by Michal at 8:12 pm on April 8**

  (B) impose requirements under the rule that the Administrator determines, consistent with the information published under subparagraph (A), are cost-effective, except where the Administrator determines that additional or different requirements described in subsection (a) are necessary to protect against the risk identified in a risk evaluation conducted under subsection (b) for the chemical substance or for a chemical substance contained in a mixture;

- **APRIL 15 sent by Michal at 10:22 am on April 15**

  (B) in selecting requirements under subsection (a) to ensure that the [chemical] substance no longer presents or will present an unreasonable risk as determined in the risk evaluation conducted under subsection (b), choose requirements from among the

one or more primary regulatory alternatives considered by the Administrator that are cost-effective based on the information published under subparagraph (A), except where the Administrator determines that none of these alternatives is sufficient to ensure that the [chemical] substance no longer presents of will present the identified unreasonable risk, in which event the Administrator shall select requirements necessary to protect fully against the risk;

	Burden relative to baseline	**Litigation Risk**
S. 697	**Lowest Analytical Burden Relative to Baseline** Roughly tracks E.O. 12866 requirements, but applies irrespective of whether action deemed "significant" under the E.O. Analytical burden limited to what is "practicable" and data inputs limited to what is "reasonably available" Statement describing how analysis was taken into account is already a baseline requirement of administrative law.	**Lowest Litigation Risk** Litigation opportunities to challenge rule roughly track what would already be available under APA under the substantial evidence standard, Scope of litigation would roughly track typical APA litigation, except that failure to include mandatory considerations in the overall discussion of why the rule is warranted would be a basis Most of these considerations would likely be raised by stakeholders in public comment anyway, which would establish an obligation for EPA to consider the issues, even if they were not statutorily specified.

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	Burden relative to baseline	Litigation Risk
Senate Offer	**Second Lowest Analytical Burden Relative to Baseline** The Senate Offer is identical to the Merged House/Senate proposal, except that the requirement for consideration of chemical alternatives has been deleted. This somewhat reduces analytical burden.	**Second Lowest Litigation Risk** The Senate Offer is identical to the Merged House/Senate proposal, except that the requirement for consideration of chemical alternatives has been deleted. This somewhat reduces the range of issues that might be the basis of litigation.
Merged House/Senate Proposal	**Third Lowest Analytical Burden Relative to Baseline** Roughly tracks E.O. 12866 requirements, but applies irrespective of whether action deemed "significant" under the E.O. Analytical burden limited to what is "practicable" and data inputs limited to what is "reasonably available" Requirement to "factor" considerations into a decisions and publish explanatory statement is already a baseline requirement of administrative law. No increase in burden from requirement to "consider and publish a statement"	**Third Lowest Litigation Risk** Litigation opportunities to challenge rule roughly track what would already be available under APA under the substantial evidence standard, Scope of litigation would roughly track typical APA litigation, except that failure to include mandatory considerations in the overall discussion of why the rule is warranted would be a basis Most of these considerations would likely be raised by stakeholders in public comment anyway, which would establish an obligation for EPA to consider the issues, even if they were not statutorily specified. Relative to H.R. 2576, list of mandatory factors is more prescriptive, somewhat increasing litigation opportunities to claim EPA failed to consider one of the points.

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	Burden relative to baseline	Litigation Risk
Supplemented Senate Offer	**Fourth Lowest Analytical Burden Relative to Baseline** The Senate Offer is identical to the Merged House/Senate proposal, except that the requirement for consideration of chemical alternatives has been deleted and a requirement to consider cost-effectiveness has been added. Overall, there is probably greater analytical burden in demonstrating that one considered cost-effectiveness than in demonstrating that one considered 1 or more chemical alternatives, so this is a slight net increase in burden.	**Fourth Lowest Litigation Risk** The Senate Offer is identical to the Merged House/Senate proposal, except that the requirement for consideration of chemical alternatives has been deleted and a requirement to consider cost-effectiveness has been added; Overall, there is probably greater litigation risk in demonstrating that one considered cost-effectiveness than in demonstrating that one considered 1 or more chemical alternatives, so this is a slight net increase in litigation risk.
Set D	**Fifth Lowest Analytical Burden Relative to Baseline** The addition of a general preference for more cost-effective options, compared to all the preceding formulations, increases the burden, because EPA would have to develop a record to explain how it overcame the preference in rulemakings where it did so.	**Fifth Lowest Litigation Risk** EPA would have to defend in court any decision to overcome the general preference for more cost-effective options.

Commented [A1]: Ranking of this formulation is conditional, and could vary depending on the context of the bill into which it was inserted. For example, other bill provisions would determine the crucial question of how many options EPA must consider – an issue not directly addressed by this language. We have ranked them under the assumption that the required scope of analysis would be comparable to that required in Set A and B.

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	Burden relative to baseline	Litigation Risk
Set A	**Sixth Lowest Analytical Burden Relative to Baseline** Set D and A seem essentially equivalent in terms of burden. We have ranked Set A as more burdensome because Set A includes a specific requirement to consider the cost-effectiveness of the proposed action and of the 1 or more primary alternatives considered in addition to the requirement in both A and D to generally give preference to more cost-effective options. But we do not see that as a meaningful additional requirement in A, and, per the comment attached to the Set D entry, if Set D were placed in a bill that did not as clearly circumscribed EPA's analytic obligation, Set D could be considerably more burdensome than A.	**Sixth Lowest Litigation Risk** EPA would have to demonstrate in court that it considered the cost-effectiveness of the proposed action and of the 1 or more primary alternatives considered, and explain any decision to overcome the general preference for more cost-effective options.
Set B	**Seventh Lowest Analytical Burden Relative to Baseline** Close call between A and B, but the substitution of efficiency for cost-effectiveness probably marginally increases the burden as compared by Set A. "Efficiency" is a more general term, so EPA would have to define what it means, and then build a record to show that the standard as defined has been met.	**Seventh Lowest Litigation Risk** The substitution of efficiency for cost-effectiveness probably increases litigation risk as compared by Set A. "Efficiency" is a more general term, so EPA would have to defend its definition of the term and also defend its conclusion that the standard as defined had been met.

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	Burden relative to baseline	Litigation Risk
Set C Version 2	**Eighth Lowest Analytical Burden Relative to Baseline** The obligation to impose requirements that are more cost-effective than the other requirements considered, unless EPA determines that other requirements are necessary to ensure no unreasonable risk, imposes a higher record burden on EPA than the preference created in Sets D, A and B. This option expresses cost-effectiveness as a relative concept, in contrast to Set C Version 1, and thereby does not impose an obligation to demonstrate that the selected requirements are cost-effective in some absolute sense. That said, the formulation is best read to require EPA to select the *most* cost-effective of the options it considered, which could require substantial analysis.	**Eighth Lowest Litigation Risk** EPA would have to demonstrate in litigation that it selected the most cost-effective of the requirements considered, or that the selected requirements were necessary to ensure no unreasonable risk – litigation burdens not present in any of the preceding formulations.

Commented [A2]: Ranking of this formulation is conditional, and could vary depending on the context of the bill into which it was inserted. For example, other bill provisions would determine the crucial question of how many options EPA must consider – an issue not directly addressed by this language. We have ranked them under the assumption that the required scope of analysis would be comparable to that required in Set A and B.

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	Burden relative to baseline	Litigation Risk
Set C Version 1	**Ninth Lowest Analytical Burden Relative to Baseline** Similar to Set C Version 2, but EPA would have to define the concept of "cost-effective" used in an absolute sense and develop a record to demonstrate that the selected requirements meet the standard as so defined.	**Ninth Lowest Litigation Risk** Similar to Set C Version 2, but EPA would have to defend its definition of the concept of "cost-effective" used in an absolute sense. Because in EPA's view the term is typically used in a relative sense, there is some concern that the term could be interpreted to mean "cost-beneficial", which is a higher standard in EPA's view than the common understanding of cost-effectiveness. EPA would also have to defend its determination that the selected requirements meet the standard as so defined.

Commented [A3]: Ranking of this formulation is conditional, and could vary depending on the context of the bill into which it was inserted. For example, other bill provisions would determine the crucial question of how many options EPA must consider – an issue not directly addressed by this language. We have ranked them under the assumption that the required scope of analysis would be comparable to that required in Set A and B.

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	Burden relative to baseline	Litigation Risk
H.R. 2576 as modified by EPA TA	**Tenth Lowest Analytical Burden Relative to Baseline** EPA must either justify substantive economic conclusion that regulation is "cost-effective" or that a non-cost-effective alternative was "necessary." Introduces a requirement to determine that the selected option is cost-effective, or, if EPA selects a non-cost-effective option, to determine that there are no protective cost-effective options; but these analytic burdens are bounded by what is practicable based on the information already required to be considered in the rulemaking. Failure to meet the safety standard is clearly a basis to deem an alternative unacceptable. Arguably also implicitly limited by the "reasonably ascertainable" caveat in paragraph (A), regarding analysis of economic consequences.	**Tenth Lowest Litigation Risk** Establishes a new legal duty, above and beyond baseline obligations to justify the rule, to either make a "cost-effectiveness" determination or a "necessity" determination. The determination could be a basis for additional litigation claims. There is some uncertainty about how many cost-effective alternatives EPA must screen and find to be unsuitable in order to conclude that a non-cost-effective alternative is necessary, but this is moderated by the "practicable" language.

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	Burden relative to baseline	Litigation Risk
H.R. 2576	**Second Highest Introduced Burden Relative to Baseline** EPA must either justify substantive economic conclusion that regulation is "cost-effective" or that a non-cost-effective alternative was "necessary." Introduces the same analytic objectives as paragraph (B) as modified, but the analysis is less clearly bounded by the information already required to be considered in the rulemaking. Failure to meet the safety standard is very likely a basis to deem an alternative unacceptable. Arguably implicitly limited by the "reasonably ascertainable" caveat in paragraph (A), regarding analysis of economic consequences.	**Second Highest Litigation Risk** Establishes a new legal duty, above and beyond baseline obligations to justify the rule, to either make a "cost-effectiveness" determination or a "necessity" determination. The determination could be a basis for additional litigation claims. There is significant uncertainty about how many cost-effective alternatives EPA must screen and find to be unsuitable in order to conclude that a non-cost-effective alternative is necessary.

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	Burden relative to baseline	Litigation Risk
April 8	**Same as HR 2576—Second Highest Introduced Burden Relative to Baseline** Same comments as on HR 2576 as the only change is to delete the phrase at the end "identified risks" and replace it with "the risk identified in a risk evaluation conducted under subsection (b) for the chemical substance or for a chemical substance contained in a mixture." Do not view this change as making any significant difference in the assessment of the burdens.	**Same as HR 2576—Second Highest Litigation Risk** Same comments as on HR 2576 as the only change is to delete the phrase at the end "identified risks" and replace it with "the risk identified in a risk evaluation conducted under subsection (b) for the chemical substance or for a chemical substance contained in a mixture." Do not view this change as making any significant difference in the assessment of the litigation risk.

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	Burden relative to baseline	Litigation Risk
April 15	**Highest Introduced Burden Relative to Baseline** EPA is required to consider at least one primary regulatory alternative that is "cost-effective." This would seem to require EPA to consider possible alternatives without limit until it finds one that is cost-effective to include as a primary regulatory option, and it is not clear what happens if there are no cost-effective alternatives. Moreover, EPA may have to include an option as a primary regulatory alternative, even if it falls well short of the standard in terms of eliminating the identified risk, simply because it's benefits outweigh its costs (e.g., perhaps labeling). EPA must determine that none of the primary regulatory alternatives is sufficient to ensure that the substance presents or will present the identified risk. EPA must then determine what requirements are "necessary" to protect fully against the risk. This language seems to add yet another determination—of insufficiency of the considered primary regulatory alternatives—to the necessity determination previously included. Arguably implicitly limited by the "reasonably ascertainable" caveat in paragraph (A),	**Highest Litigation Risk** Establishes new legal duties, above and beyond baseline obligations to justify the rule, to identify cost-effective options, to determine whether they are sufficient to ensure that the chemical no longer presents or will present the identified risks, and to determine which selected non-cost effective option is necessary. These determinations could be a basis for additional litigation claims. There is significant uncertainty about how many cost-effective alternatives EPA must screen and find to be unsuitable in order to conclude that cost effective alternatives are not sufficient to ensure that the chemical no longer presents or will present the identified risk.

	regarding analysis of economic consequences.	

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/13/2016 8:11:38 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: RE: Sen. Markey TSCA request on section 5 (4-13)

Thanks – will pass along

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Wednesday, April 13, 2016 4:09 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Markey TSCA request on section 5 (4-13)

Yes – we've agreed to allow the removal of cost considerations from the test marketing exemptions.... Thank you!

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Wednesday, April 13, 2016 4:05 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA request on section 5 (4-13)

Michal,
This attached TA responds to the request on the revised section 5.

This draft does a good job of addressing the TA from yesterday. We only have a few further drafting suggestions, and we included a comment double checking that you intended to include cost considerations into the 5(h)(1) analysis -- there's no "without consideration of cost" language there.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any questions. Thanks,

Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>
Date: April 13, 2016 at 9:49:40 AM EDT
To: "Sven-Erik Kaiser (Kaiser.Sven-Erik@epamail.epa.gov)" <Kaiser.Sven-Erik@epamail.epa.gov>
Subject: section 5

Sven

Attached section 5 – the HLC version – as modified by the TA you sent us on the SLC version (we too are annoyed and tired –sorry about the parallel tracking here.). we'd like your review of this before we send it to the House. Section 6 will follow likely around mid-day. Rapid turnaround appreciated.

Thanks
Michal

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/8/2016 9:22:54 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TA on Nomenclature issues
Attachments: Pages from 1985 Inventory Listings.pdf; 4-8 draft nomenclature TA v2.docx; Markey.TSCA TA.nomenclature.4.8.16.docx

Michal,
This TA responds to the request on nomenclature. Also attached is text on statutory mixtures that might be helpful in considering the TA.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Sunday, April 03, 2016 6:18 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Latest on nomenclature

Some changes here. Won't address all your questions but I'm hoping the "without limitation" tweak helps. Let me know (after section 5 and 4).

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

With respect to (A)(iii):

The six statutory mixture listings on the Inventory define particular circumstances in which the manufacture of a new chemical substance will not be treated as the manufacture of a new chemical substance. They seem to have been established for pragmatic reasons in the late 1970s. Industry may construe the term "statutory mixture" more generally than EPA would, as encompassing a wider range of scenarios where they believe it is impractical or otherwise unwarranted for EPA to review the manufacture of a new chemical substance that is, in fact, being manufactured.

The overall effect and intent of (A)(iii) remains opaque to EPA. We currently recognize the six statutory mixtures identified in the draft legislation as statutory mixtures on the Inventory, although EPA guidance is confusing in this area and could be read to recognize additional statutory mixtures. In our view the statutory mixtures include what is described in their Inventory definitions (see attached) and do not include what is not described in their Inventory definitions. Overall, this is a confusing area, and industry would likely argue with EPA about: (1) the interpretation of the Inventory definitions for the six identified substances that EPA recognizes are statutory mixtures, (2) whether there are other statutory mixtures; and (3) the consequences of being a statutory mixture.

With or without the highlighted text, (A)(iii) does not provide clear direction to EPA on any of these issues. If the intent is to lock in existing statutory mixture listings, that will undoubtedly generate arguments as to what listings qualify and what the scope of those listings is. Moreover, (A)(iii) arguably changes the scope of existing statutory mixture listings: it provides that chemical components are covered by the listing only when present in the mixtures, but, as stated above, the scope of the statutory mixtures is governed by the terms of the listings, and it is not clear that all require the chemicals to be present in the mixtures to qualify. Moreover, the six identified statutory mixture listings were added to the initial inventory decades ago, along with 60,000 other chemical names, without opportunity for significant deliberation and consideration of consequences; EPA has substantially more information about and understanding of chemical substances at this point and questions whether it makes sense to lock these listings (and, industry will argue, others) into the statute.

If the intent is simply to ensure that EPA treats substances as statutory mixtures if they are within the scope of the existing Inventory definitions, and does not treat substances as statutory mixtures if they are outside the scope of the existing Inventory definitions, then it is unclear why (A)(iii) is necessary at all: this is already self-evident. Whether or not the intent is to alter the status quo, (A)(iii) makes the current confusion worse, because it does not communicate to EPA what exactly, if anything, it should be doing differently from the status quo. At the same time, it provides a new basis for industry to litigate any nomenclature decision that EPA may make in the future that they disagree with, on the grounds that EPA is failing to recognize a statutory mixture that Congress intended to be recognized.

EPA suggests that the drafters' intent may be better effectuated by one of the following approaches:

- **Delete (A)(iii);**
- **Redraft (A)(iii) entirely**, starting with a clear statutory definition of what a statutory mixture really is. (We recognize that EPA's own lack of clarity about what a "statutory mixture" is would make this approach challenging); or
- **Replace (A)(iii)**, with a general direction to complete a process, subject to public comment, of reviewing whether the definitions of the six identified Inventory listings should be revised.

(Note that this would not be a rulemaking process, because EPA's authority to revise the Inventory under § 8(b) is an order authority).

With respect to (B)(i):

The newly revised (B)(i) language would provide a much stronger basis for industry to argue that EPA needs to treat new chemical substances that are arguably similar to existing chemical substances as themselves being existing chemical substances. (B)(i) is no longer limited to "existing guidance" that allows for multiple nomenclature conventions. Since we believe there is no such existing EPA TSCA guidance, deleting this limitation transforms (B)(i) from an inoperative provision to one that arguably requires EPA to defer to industry-developed nomenclature conventions, including nomenclature conventions affecting the scope of new chemical review.

As revised, EPA must now take general notice of "the nomenclature conventions for substances," which could mean every nomenclature convention that exists, regardless of source. Any party could argue that a particular non-EPA document on naming and classifying chemical substances (e.g., one developed by a trade association for the purposes of its members) is a "nomenclature convention" that EPA must accommodate. If such a third-party naming convention happens to treat a whole category of chemical substances as a single chemical substance, then it could be argued that EPA must develop its own conforming guidance under (B)(i)(II) to "maintain" the third party naming convention under (B)(i)(I). Under (B)(i)(II)(bb), manufacturers of new chemical substances that share a category description with existing chemical substances could then "rely on" that EPA guidance for purposes of avoiding new chemical review of their new chemical substance.

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EPA TA on nomenclature (4/8/16)

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As revised, EPA must now take general notice of "the nomenclature conventions for substances," which could mean every nomenclature convention that exists, regardless of source. Any party could argue that a particular non-EPA document on naming and classifying chemical substances (e.g., one developed by a trade association for the purposes of its members) is a "nomenclature convention" that EPA must accommodate. If such a third-party naming convention happens to treat a whole category of chemical substances as a single chemical substance, then it could be argued that EPA must develop its own conforming guidance under (B)(i)(II) to "maintain" the third party naming convention under (B)(i)(I). Under (B)(i)(II)(bb), manufacturers of new chemical substances that share a category description with existing chemical substances could then "rely on" that EPA guidance for purposes of avoiding new chemical review of their new chemical substance.

65996-81-8*
Fuel gases, coke-oven
The gas evolved from the high temperature (greater than 700°C (1292°F)) destructive distillation of coal after the removal of high temperature coal tar, coke oven light oil, and ammonia liquor. Composed primarily of hydrogen and methane. May contain ammonia, hydrogen sulfide, and low molecular weight hydrocarbons.

65996-82-9*
Tar oils, coal
Synonym: Chemical Oil (Coal), Tar Acid Oil (Coal)
The distillate from high temperature coal tar having an approximate distillation range of 130°C to 250°C (266°F to 410°F). Composed primarily of naphthalene, alkylnaphthalenes, phenolic compounds, and aromatic nitrogen bases.

65996-83-0*
Extracts, coal tar oil alkaline
Synonym: Chemical Oil Alkaline Extract (Coal)
The extract from coal tar oil produced by an alkaline wash such as aqueous sodium hydroxide. Composed primarily of the alkali salts of various phenolic compounds.

65996-84-1*
Tar bases, coal, crude
The reaction product obtained by neutralizing coal tar base extract oil with an alkaline solution, such as aqueous sodium hydroxide, to obtain the free bases. Composed primarily of a complex combination of pyridine, quinoline, and their alkyl derivatives.

65996-85-2*
Tar acids, coal, crude
The reaction product obtained by neutralizing coal tar oil alkaline extract with an acidic solution, such as aqueous sulfuric acid, to obtain the free acids. Composed primarily of phenol, cresols, and xylenols.

65996-86-3*
Extract oils (coal), tar base
The extract from coal tar oil alkaline extract residue produced by an acidic wash such as aqueous sulfuric acid after distillation to remove naphthalene. Composed primarily of the acid salts of various aromatic nitrogen bases including pyridine, quinoline, and their alkyl derivatives.

65996-87-4*
Extract residues (coal), tar oil alk.
Synonym: Chemical Oil Alkaline Extract Residue
The residue obtained from coal tar oil by an alkaline wash such as aqueous sodium hydroxide after the removal of crude coal tar acids. Composed primarily of naphthalenes and aromatic nitrogen bases.

65996-88-5*
Benzol forerunnings (coal)
The distillate from coke oven light oil having an approximate distillation range below 100°C (212°F). Composed primarily of C_4 to C_6 aliphatic hydrocarbons.

65996-89-6*
Tar, coal, high-temp.
The condensation product obtained by cooling, to approximately ambient temperature, the gas evolved in the high temperature (greater than 700°C (1292°F)) destructive distillation of coal. A black viscous liquid denser than water. Composed primarily of a complex mixture of condensed ring aromatic hydrocarbons. May contain minor amounts of phenolic compounds and aromatic nitrogen bases.

65996-90-9*
Tar, coal, low-temp.
The condensation product obtained by cooling, to approximately ambient temperature, the gas evolved in low temperature (less than 700°C (1292°F)) destructive distillation of coal. A black viscous liquid denser than water. Composed primarily of condensed ring aromatic hydrocarbons, phenolic compounds, aromatic nitrogen bases, and their alkyl derivatives.

65996-91-0*
Distillates (coal tar), upper
The distillate from high temperature coal tar having an approximate distillation range of 220°C to 450°C (428°F to 842°F). Composed primarily of three to four membered condensed ring aromatic hydrocarbons.

65996-92-1*
Distillates (coal tar)
The distillate from high temperature coal tar having an approximate distillation range of 130°C to 450°C (266°F to 842°F). Composed primarily of two to four membered condensed ring aromatic hydrocarbons, phenolic compounds, and aromatic nitrogen bases.

65996-93-2*
Pitch, coal tar, high-temp.
The residue from the distillation of high temperature coal tar. A black solid with a softening point from 40°C to 180°C (104°F to 356°F). Composed primarily of a complex combination of three or more membered condensed ring aromatic hydrocarbons.

65996-94-3*
Phosphate rock and Phosphorite, calcined
Synonym: Phosphate rock, calcined
Substance obtained by heating naturally occurring phosphate rock to 732°C to 816°C (1350°F to 1500°F) in a fluidized bed or other suitable device for oxidizing carbonaceous matter. Characterized by upgraded phosphorus content and reduced hydrocarbon levels.

65996-95-4*
Superphosphates, concd.
Synonym: Double superphosphate, treble superphosphate, triple superphosphate
Substance obtained by acidulating phosphate rock with phosphoric acid. Normally characterized as containing 40% or more available phosphoric oxide (P_2O_5). Composed primarily of calcium phosphate.

65996-96-5*
Terpenes and Terpenoids, turpentine-oil, α-pinene fraction
The hydrocarbon fraction distilled from oil of turpentine. Contains greater than 80% α-pinene, the remainder being other terpene hydrocarbons.

65996-97-6*
Terpenes and Terpenoids, turpentine-oil, β-pinene fraction
The hydrocarbon fraction distilled from oil of turpentine or produced by the isomerization of α-pinene. Contains greater than 70% β-pinene. Other major components being limonene, α-pinene, camphene, myrcene. May contain other acyclic, monocyclic, and bicyclic terpenes.

65996-98-7*
Terpenes and Terpenoids, limonene fraction
Synonym: Terpenes, 80% or greater Limonene Fraction
A complex combination of terpenes derived from oil of turpentine or citrus oils by fractionation or isomerization of other terpene fractions. Contains at least 80% limonene, the remainder being other terpene hydrocarbons. May contain trace amounts of alcohols, ethers, aldehydes, or ketones.

65996-99-8*
Terpenes and Terpenoids, turpentine-oil, limonene fraction
Synonym: Oil of Turpentine, 50% or greater limonene fraction
A complex combination of terpenes derived from oil of turpentine. Contains at least 50% limonene, the remainder being phellandrenes, terpinenes, terpinolene, cineoles.

65997-00-4*
Terpenes and Terpenoids, turpentine-oil, terpinolene fraction
Synonym: Oil of turpentine, 80% or greater terpinolene fraction
A complex combination of terpenes derived from oil of turpentne. Contains at least 80% terpinolene, the remainder being mixed terpene hydrocarbons.

65997-02-6*
Wastewater, tall-oil soap acidulation
Synonym: Spent acid from crude tall oil soap acidulation
The aqueous layer formed by acidulation of tall-oil soap with sulfuric acid during the production of tall oil. Composed primarily of a solution of sodium sulfate, the remaining being lignin and tall oil.

65997-03-7*
Fatty acids, tall-oil, low-boiling
Synonym: Tall oil heads
The low boiling fraction obtained by the distillation of tall oil. Contains fatty acids such as palmitic, stearic, oleic and linoleic as well as neutral materials.

65997-15-1*
Cement, portland, chemicals
Synonym: Chemical substances manufactured in the production of portland cement
Portland cement is a mixture of chemical substances produced by burning or sintering at high temperatures (greater than 1200°C) raw materials which are predominantly calcium carbonate, aluminum oxide, silica, and iron oxide. The chemical substances which are manufactured are confined in a crystalline mass. This category includes all of the chemical substances specified below when they are intentionally manufactured in the production of Portland cement. The primary members of the category are Ca_2SiO_4 and Ca_3SiO_5. Other compounds listed below may also be included in combination with these primary substances.

$CaAl_2O_4$	$Ca_2Al_2SiO_7$
$CaAl_4O_7$	$Ca_4Al_6SO_{16}$
$CaAl_{12}O_{19}$	$Ca_{12}Al_{14}Cl_2O_{32}$
$Ca_3Al_2O_6$	$Ca_{12}Al_{14}F_2O_{32}$
$Ca_{12}Al_{14}O_{33}$	$Ca_4Al_2Fe_2O_{10}$
CaO	$Ca_6Al_4Fe_2O_{15}$
$Ca_2Fe_2O_5$	

65997-16-2*
Cement, alumina, chemicals
Synonym: Chemical substances manufactured in the production of high-alumina cement
High-Alumina cement is a mixture of chemical substances produced by burning or sintering at high temperature (greater than 1200°C) raw materials which are predominantly calcium carbonate, aluminum oxide, silica, and iron oxide. The chemical substances which are manufactured are confined in a crystalline mass. This category includes all of the chemical substances specified below when they are intentionally manufactured in the production of high-alumina cement. The primary members of this category are

$CaAl_2O_4$, $Ca_4Al_2FeO_{10}$, $Ca_{12}Al_{14}O_{33}$, and Ca_2SiO_4. Other compounds listed below may also be included in the combination with these primary substances.

$CaAl_4O_7$	$Ca_2Al_2SiO_7$
$CaAl_{12}O_{19}$	$Ca_4Al_6SO_{16}$
$Ca_3Al_2O_6$	$Ca_{12}Al_{14}Cl_2O_{32}$
CaO	$Ca_{12}Al_{14}F_2O_{32}$
Ca_3SiO_5	$Ca_6Al_4Fe_2O_{15}$
$Ca_2Fe_2O_5$	

65997-17-3*

Glass, oxide, chemicals

Synonym: Chemical substances manufactured in the production of inorganic glass

This category encompasses the various chemical substances manufactured in the production of inorganic glasses. For purposes of this category, "glass" is defined as an amorphous, inorganic, transparent, translucent or opaque material traditionally formed by fusion of sources of silica with a flux, such as an alkali-metal carbonate, boron oxide, etc. and a stabilizer, into a mass which is cooled to a rigid condition without crystallization in the case of transparent or liquid-phase separated glass or with controlled crystallization in the case of glass-ceramics. The category consists of the various chemical substances, other than by-products or impurities, which are formed during the production of various glasses and concurrently incorporated into a glass mixture. All glasses contain one or more of these substances, but few, if any, contain all of them. The elements listed below are principally present as components of oxide systems but some may also be present as halides or chalcogenides, in multiple oxidation states, or in more complex compounds. Trace amounts of other oxides or chemical compounds may be present. Oxides of the first seven elements listed* comprise more than 95 percent, by weight, of the glass produced.

Aluminum*	Lanthanum
Boron*	Lead
Calcium*	Lithium
Magnesium*	Manganese
Potassium*	Molybdenum
Silicon*	Neodymium
Sodium*	Nickel
Antimony	Niobium
Arsenic	Nitrogen
Barium	Phosphorus
Bismuth	Praseodymium
Cadmium	Rubidium
Carbon	Selenium
Cerium	Silver
Cesium	Strontium
Chromium	Sulfur
Cobalt	Tellurium
Copper	Tin
Germanium	Titanium
Gold	Tungsten
Holmium	Uranium
Iron	Vanadium
	Zinc

65997-18-4*

Frits, chemicals

Synonym: Chemical substances manufactured in the production of frit

Frit is a mixture of inorganic chemical substances produced by rapidly quenching a molten, complex combination of materials, confining the chemical substances thus manufactured as nonmigratory components of glassy solid flakes or granules. This category includes all of the chemical substances specified below when they are intentionally manufactured in the production of frit. The primary members of this category are oxides of some or all of the elements listed below. Fluorides of these elements may also be included in combination with these primary substances.

Aluminum	Manganese
Antimony	Molybdenum
Arsenic	Neodymium
Barium	Nickel
Bismuth	Niobium
Boron	Phosphorus
Cadmium	Potassium
Calcium	Silicon
Cerium	Silver
Chromium	Sodium
Cobalt	Strontium
Copper	Tin
Gold	Titanium
Iron	Tungsten
Lanthanum	Vanadium
Lead	Zinc
Lithium	Zirconium
Magnesium	

65997-19-5*

Steel manufacture, chemicals

Synonym: Chemical substances manufactured as a part of steel

This category includes the chemical substances which are manufactured as part of steel and alloy steels. The following list identifies those elements which may exist in steel or which may comprise compounds present in steel or alloy steels. Aluminum, beryllium, boron, calcium, carbon, cerium, chromium, cobalt, copper, hafnium, iron, lanthanum, lead, magnesium, manganese, molybdenum, nickel, niobium, nitrogen, oxygen, phosphorus, selenium, silicon, sulfur, tantalum, tin, titanium, tungsten, vanadium, yttrium, zinc, zirconium.

65997-20-8*

Tannins, recovered

A complex combination of vegetable tanning materials recovered from the tanning of leather. It consists of natural tannins, which are predominantly polyphenolic compounds, and/or synthetic tannins, such as aromatic sulfonic acid derivatives.

66071-92-9*

Sulfite liquors and Cooking liquors, spent

Synonym: Spent pulping liquor

The aqueous solution resulting from the reaction of lignocellulosic substances (wood or other agricultural fiber sources) with one or more pulping chemicals including those used in the kraft, sulfite, semichemical or other pulping processes. Composition is highly variable and includes excess pulping chemicals, dissolved and degraded cellulose, hemicellulose and lignin.

66071-94-1*

Corn, steep liquor

Synonym: Condensed fermented corn extractives; Corn steepwater

Substance obtained by the partial removal of water from the liquid resulting from steeping corn in a water and sulphur dioxide solution which is allowed to ferment by the action of naturally occurring lactic acid-producing microorganisms.

66071-96-3*

Glutens, corn

Synonym: Corn gluten meal

The dried residue from corn after the removal of the larger part of the starch and germ and the separation of the bran in the wet-milling manufacture of corn starch or syrup, or by enzymatic treatment of the endosperm.

66402-68-4*

Ceramic materials and wares, chemicals

Synonym: Chemical substances manufactured in the production of ceramics

This category encompasses the various chemical substances manufactured in the production of ceramics. For purposes of this category, a ceramic is defined as a crystalline or partially crystalline, inorganic, non-metallic, usually opaque substance consisting principally of combinations of inorganic oxides of aluminum, calcium, chromium, iron, magnesium, silicon, titanium, or zirconium which conventionally is formed first by fusion or sintering at very high temperatures, then by cooling, generally resulting in a rigid, brittle monophase or multiphase structure. (Those ceramics which are produced by heating inorganic glass, thereby changing its physical structure from amorphous to crystalline but not its chemical identity are not included in this definition.) This category consists of chemical substances other than by-products or impurities which are formed during the production of various ceramics and concurrently incorporated into a ceramic mixture. Its composition may contain any one or a combination of these substances. Trace amounts of oxides and other substances may be present. The following representative elements are principally present as oxides but may also be present as borides, carbides, chlorides, fluorides, nitrides, silicides, or sulfides in multiple oxidation states, or in more complex compounds.

Aluminum	Lithium
Barium	Magnesium
Beryllium	Manganese
Boron	Phosphorus
Cadmium	Potassium
Calcium	Silicon
Carbon	Sodium
Cerium	Thorium
Cesium	Tin
Chromium	Titanium
Cobalt	Uranium
Copper	Yttrium
Hafnium	Zinc
Iron	Zirconium

67254-74-4*

Naphthenic oils

Liquid naphthenic hydrocarbons from petroleum.

67674-13-9*

Petrolatum (petroleum), oxidized, partially deacidified

A complex combination of organic compounds, predominantly high molecular weight carboxylic acids, obtained by air oxidation of petrolatum from which the stronger acid components have been removed by aqueous alkaline extraction.

67674-16-2*

Hydrocarbon waxes (petroleum), oxidized, partially deacidified

A complex combination of organic compounds, predominantly high molecular weight carboxylic acids, obtained by air oxidation of

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/29/2016 1:50:25 PM
To: Couri, Jerry [JerryCouri@mail.house.gov]
Subject: Re: TA request on TSCA section 5

Jerry,
Thanks- we see a couple of ways this could go, any availability for a call? Best,
Sven

On Apr 29, 2016, at 9:45 AM, Couri, Jerry <JerryCouri@mail.house.gov> wrote:

Part of it relates to whether putting 5(e)(1)(A) into 5(a)(3)(B), what would be the effect of not changing 5(e) further and if change necessary, how much of the previous TA stands?

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Thursday, April 28, 2016 8:55 PM
To: Couri, Jerry
Subject: Re: TA request on TSCA section 5

Jerry,
This TA responds to the request on section 5(e).

We sent suggested changes both to the new 5(a)(3)(B) (to align with 5(e)) and to 5(e)(1)(A) (e.g., to remove the language about substantial production, release and exposure, which is not part of the 5(a)(3)(B) finding under your draft). Do you have specific questions about the changes we suggested to the lead in to 5(e)? See attachments for the most recent section 5 TA.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any additional questions. Thanks,

Sven

Sven-Erik Kaiser

U.S. EPA

Office of Congressional and Intergovernmental Relations

1200 Pennsylvania Ave., NW (1305A)

Washington, DC 20460

202-566-2753

On Apr 28, 2016, at 5:53 PM, Couri, Jerry <JerryCouri@mail.house.gov> wrote:

Sven:

Thanks to you and the folks at EPA for the TA on section 5. We have a follow-up question on what you sent to us:

If we change the wording in proposed new section 5(a)(3)(B) to match existing section 5(e) -- as I think the Agency's TA suggests, would we need to change the lead in to existing 5(e)?

Thanks.

- <!--[if !supportLists]--><!--[endif]-->Jerry

Gerald S. Couri
Senior Environmental Policy Advisor | Committee on Energy and Commerce
U.S. House of Representatives
2125 Rayburn Building | 202.226.9603 (direct)

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/11/2016 10:24:16 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TA request on section 6 implementation dates for bans/phaseouts
Attachments: Markey.TSCA TA.section 6 dates for bans and phaseouts.docx

Michal,
This responds to your TA request on section 6 implementation dates for bans and phaseouts. Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Monday, March 07, 2016 1:19 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: TA request - Markey implementation dates for bans/phaseouts

Sven

Again, for after the other pending TA requests, and again, in the spirit of trying to come up with some alternative options in case they are needed. This is an effort to clarify the industry compliance date language but provide an explicit way for EPA to consider long product cycles (like automobiles, for example).

Pls let me know of any workability or other concerns.

Thanks
Michal

This language is provided EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

TA Request: This is an effort to clarify the industry compliance date language but provide an explicit way for EPA to consider long product cycles (like automobiles, for example). Please let me know of any workability or other concerns.

(a) EFFECTIVE DATE.—(1) The Administrator shall specify in any rule under subsection (a) the date on which it shall take effect, ~~which date shall be as soon as feasible~~ and dates by which compliance is mandatory, which

(A) shall be as soon as practicable, but ~~which shall require full implementation of all restrictions~~ not later than 4 years after the date of promulgation of the rule, except in a case of a use exempted under subsection(g);

(B) shall provide for a reasonable transition period, including for restrictions that impose a ban or phase-out of the chemical substance, subject to the condition that full compliance with all restrictions shall be required within the timeframe established in (a)(1)(A);

(C) as determined by the Administrator, may vary for different affected persons; and

(D) following a determination by the Administrator that compliance is technologically or economically infeasible within the timeframe specified in subparagraph (A), shall provide up to an additional 18 months for compliance to be mandatory.

Commented [A1]: Edits move this idea from (A) to (B), where it seems to more squarely prevent arguments that transition timeframes could extend beyond 4 years.

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(6)(g)(3)

ANALYIS IN CASE OF BAN OR PHASE_OUT – In determining whether an exemption should be granted for a chemical substance for which a ban or phase-out is proposed, the Administrator shall take into consideration, to the extent practicable based on reasonably available information, the quantifiable and non-quantifiable costs and benefits of the 1 or more alternatives to the chemical substance the Administrator determines to be technically and economically feasible and most likely to be used in place of the chemical substance under the conditions of use, and, for an exemption from a proposed ban or phase-out of a use of a chemical substance in an article, whether the ban or phase-out would require the re-design of the article or another article of which it is a component and whether the proposed ban or phase-out can be practicably accomplished for the use of the chemical substance in such~~the~~ articles by the date required by the rule~~the Administrator specifies to be mandatory~~.

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Commented [A2]: It is difficult to evaluate this text without knowing whether articles are addressed elsewhere in the bill. Is this text in lieu of the kinds or articles analysis that has factored into the basic rulemaking decisionmaking in the bills, or in addition to it? In addition, note that, while your goal is to provide "an explicit way for EPA to consider long product cycles", this provision would not expand EPA's authority to grant an exemption, since the grounds for exemption are specified elsewhere (6(d)(5)(A) in 697). If the latter, not clear why it is necessary. (On a related note: we have always found this 6(g)(3) provision a little confusing, since to some extent it seems to require in the exemption context re-analysis of the underlying rule. This raises the question in our minds as to whether this is the best place to put this provision.) That all said, with probably could be workable.

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~~(D)~~

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/21/2016 10:06:21 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: RE: Sen. Markey TSCA TA Request on nomenclature language

Michal,
Thanks for the insight. I'll pass along to the team. Best,
Sven

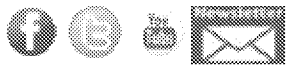
Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Thursday, April 21, 2016 6:05 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Markey TSCA TA Request on nomenclature language

Thanks. sorry to ask, but for whatever reason they are insisting on all the savings clauses being added to even our language.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey



From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Thursday, April 21, 2016 6:04 PM
To: Freedhoff, Michal (Markey)
Subject: RE: Sen. Markey TSCA TA Request on nomenclature language

Michal – got it – checking. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Thursday, April 21, 2016 6:02 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: FW: Sen. Markey TSCA TA Request on nomenclature language

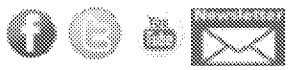
Sven

Does the attached second document that includes language that was proposed to the House by the Senate 1) present any of the problems described in your attached TA document on the language the House proposed to the Senate or 2) require a savings clause to protect against any unintended consequences?

Thanks
Michal

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey



From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Thursday, April 21, 2016 5:35 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA Request on nomenclature language

Michal,
The attached TA responds to the request on nomenclature language (4-20).

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments. Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Wednesday, April 20, 2016 6:33 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Fw: confidential draft

Pls review. Section 6 coming soon.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

From: McCarthy, David <David.McCarthy@mail.house.gov>
Sent: Wednesday, April 20, 2016 6:29 PM
To: Jackson, Ryan (Inhofe); Karakitsos, Dimitri (EPW); Poirier, Bettina (EPW); Black, Jonathan (Tom Udall); Freedhoff, Michal (Markey)
Cc: Cohen, Jacqueline; Sarley, Chris; Couri, Jerry; Richards, Tina; Kessler, Rick
Subject: FW: confidential draft

On the House side we've been working hard to develop some fixes that can make a bi-par House vote possible:

On section 26 we will go with the draft as is, including Senate science language.

On section 6 (April12 draft) - On page 2 – keep the factors to consider for selecting chemicals for prioritization but drop the requirement that EPA do a rulemaking for a year to articulate those standards.

- On page 4 keep the low priority designation but in the description of low priority substances, change "not likely to present" to "likely not to present"

- On page 4, delete the distinction for inactive substances

- On page 6-7, delete paragraph (C) –
- On page 8, line 13 delete (i) [info request] and (ii) [notice and comment]
- On page 10, line 17, delete (B) This is covered by our section 26
- On page 12 – delete notice and comment on requests for risk evaluation. Seems to suggest that EPA prioritizes manufacturer risk evaluations, instead of first-come first-served. -

In the new language from Dimitri and Michal, keep the new arrangement for (c)(2)(A) [including new Senate treatment of "cost-effective", etc] but in (c)(2)(A)(iv)(II) delete "quantifiable and non-quantifiable"

On articles in 6 delete "or category of articles" in one place but not both. It's not needed where bracketed below.
"(D) ARTICLES.—In selecting among prohibitions and other restrictions, the Administrator shall apply such prohibitions or other restrictions to an article or category of articles containing the chemical substance or mixture only to the extent necessary to address the identified risks from exposure to the chemical substance or mixture from the article [or category of articles], so that the substance or mixture does not present an unreasonable risk identified in the risk evaluation conducted in accordance with subsection (b)(4)(A).

We're still working on 5, including considering a change to your SNU articles language.

-

On section 8:
Use either the short or long versions that you have sent us, but include the 2 savings clauses that were drafted earlier and which you guys have.

In section 14 some concerns about the distinction being drawn between non-emergency and emergency situations – if a release of the chemical substance has occurred or one or more people being treated have been exposed, it would seem like you have moved into the emergency category.

- On page 22, it might make sense to drop the distinction for inactive substances if we drop the extra bar for designating those as high priority.

-

On section 4:

- Permit section 4(a) testing when a chemical may present an unreasonable risk by order as well as by rule. Keep tiered testing, but tweak it:

"(4) TIERED TESTING.—When requiring the development of new information under this subsection, the Administrator shall *consider employing* a tiered screening and testing process, under which the results of

screening-level tests or assessments of available information inform the decision as to whether 1 or more additional tests are necessary, unless information available to the Administrator justifies more advanced testing of potential health or environmental effects or potential exposure without first *considering* [conducting] screening-level testing.'';

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/23/2016 8:19:59 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
CC: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]; Deveny, Adrian (Merkley) [Adrian_Deveny@merkley.senate.gov]
Subject: Sen. Markey TSCA TA Request on Section 4

Michal – got it – checking. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Wednesday, March 23, 2016 3:48 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Cc: Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>; Deveny, Adrian (Merkley) <Adrian_Deveny@merkley.senate.gov>
Subject: Section 4

Sven

In the list of items under senate 4(a)(1) - list of 4 conditions where there is testing allowed by order. In discussing a hybrid House/Senate concept, a question was raised about whether RULES could be required for some or all of the 4(1)(B) items rather than orders. Tell us of any downsides - argument is that epa is already writing a 6(a) rule that may include a restriction related to testing, and same w potentially 5(d). What we'd like is your assessment of scenarios in which a requirement to do rules rather than orders in 4(1)(B) would be a problem. It may be that all scenarios are problems - but it may also be that there are some scenarios where it would not be.

Thanks
M

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/15/2016 7:07:18 PM
To: Michal_Freedhoff@markey.senate.gov
Subject: Low Hazard -- Section 6

Michal,
This responds to the request on "low hazard."

Subsection (j) is titled "Low Hazard," but the text makes clear that EPA cannot so designate a chemical substance unless there is evidence demonstrating that the chemical substance poses *no hazard* to human health or the environment. Strictly speaking, there is no chemical substance that poses no possible hazard: this poses implementation problems. EPA would probably still get many requests from industry arguing that particular chemical substances pose no hazard, and that Congress intended EPA to construe "no hazard" as meaning "low hazard." It appears that there would be no fees available to cover the cost of processing such requests, so this provision could be a potential drain on resources. Note also, that subsection (k)(2) directs EPA to remove chemical substances from the Work Plan if they are later found to present a "low hazard," under subsection (j), which would actually require finding that they "do not pose a hazard," at all. This could be construed as reflecting Congressional concern that certain substances on the Work Plan pose no hazard to human health or the environment. EPA does not believe that any chemical substances on the Work Plan are likely to be demonstrated to pose no hazard.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any questions. Thanks,

Sven

Sven-Erik Kaiser

U.S. EPA

Office of Congressional and Intergovernmental Relations

1200 Pennsylvania Ave., NW (1305A)

Washington, DC 20460

202-566-2753

From: "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>
Date: April 15, 2016 at 1:02:53 PM EDT
To: "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov>
Subject: Re: Sen. Markey TSCA TA on Jackie's 6

And 6. We need the views on 6 and not 5. We don't like it in 5.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

From: Kaiser, Sven-Erik

Sent: Friday, April 15, 2016 12:57 PM

To: Freedhoff, Michal (Markey)

Subject: Re: Sen. Markey TSCA TA on Jackie's 6

Michal,

Just to be sure- the "low hazard" is in section 5 - right? Thanks,

Sven

On Apr 15, 2016, at 12:41 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Also pls look at her new "low hazard" thing in 6.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

From: Kaiser, Sven-Erik

Sent: Friday, April 15, 2016 12:25 PM

To: Freedhoff, Michal (Markey)

Subject: Sen. Markey TSCA TA on Jackie's 6

Michal,

This TA responds to the request on Jackie's draft section 6., re: the alternatives analysis language, p11 , line 5.

This language is consistent with the type of analysis that EPA would already do in the absence of statutory mandate, and we do not see a significant issue with it. That being said, one way to soften the requirement would be to replace "determine" (p.11, line 10) with "consider." See text below. Doing so would reduce opportunities for litigation on the sufficiency of EPA's "determination" – a separate administrative action that can be challenged.

''(C) based on the information published under subparagraph (A), in deciding whether to prohibit or restrict in a manner that substantially prevents a specific use of a chemical substance or mixture and in setting an appropriate transition period for such action, ~~determine~~ consider whether technically and economically feasible alternatives that benefit health or the environment, compared to the use so proposed to be prohibited or restricted, will be reasonably available as a substitute when the proposed prohibition or other restriction takes effect;

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any questions. Thanks,

Sven

Sven-Erik Kaiser

U.S. EPA

Office of Congressional and Intergovernmental Relations

1200 Pennsylvania Ave., NW (1305A)

Washington, DC 20460

202-566-2753

From: "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>
Date: April 15, 2016 at 10:29:08 AM EDT
To: "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov>
Subject: Re: Jackie's 6

Also pls see alternatives analysis p 11 line 5. We need to include something like this. Need this back asap. I was hoping to limit this language to bans and phaseouts but in the past you've said you would do this analysis anyway and want your take on this.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

From: Kaiser, Sven-Erik

Sent: Friday, April 15, 2016 10:23 AM

To: Freedhoff, Michal (Markey)

Subject: Re: Jackie's 6

Got it - checking

On Apr 15, 2016, at 10:22 AM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

On section 6 pls esp look at p 10 lines 14 and on. And rank on the chart? Asap would be good.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

<Jackie section 6.pdf>

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/24/2016 1:26:51 AM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Re: Sen. Markey TSCA TA on House section 6 (4-22)

Michal - got it. Thanks for clarifying.
Sven

On Apr 23, 2016, at 9:22 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

In conforming changes at back there are a number of places where hlc wants to know if we shd add 6(i) orders to a list of orders now covered by various sections. In some places we think yes and in others no. If you guys have a view let me know. Thx.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

From: Kaiser, Sven-Erik
Sent: Saturday, April 23, 2016 9:19 PM
To: Freedhoff, Michal (Markey)
Subject: Re: Sen. Markey TSCA TA on House section 6 (4-22)

Michal - I raised section 6(i) with the team. They weren't sure what the issue was and we didn't spot any issues on that when reviewing section 6. Please let me know if there is a question on 6(i) needing TA attention. Thanks,
Sven

On Apr 23, 2016, at 9:13 PM, Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov> wrote:

Michal,
This TA responds to the request on House section 6 (4-22).

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser

U.S. EPA

Office of Congressional and Intergovernmental Relations

1200 Pennsylvania Ave., NW (1305A)

Washington, DC 20460

202-566-2753

<Markey.TSCA TA.House Section 6 (4-22).docx>

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/13/2016 8:05:26 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA request on section 5 (4-13)
Attachments: Markey.TSCA TA.section 5 (4-13).docx

Michal,
This attached TA responds to the request on the revised section 5.

This draft does a good job of addressing the TA from yesterday. We only have a few further drafting suggestions, and we included a comment double checking that you intended to include cost considerations into the 5(h)(1) analysis -- there's no "without consideration of cost" language there.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>
Date: April 13, 2016 at 9:49:40 AM EDT
To: "Sven-Erik Kaiser (Kaiser.Sven-Erik@epamail.epa.gov)" <Kaiser.Sven-Erik@epamail.epa.gov>
Subject: section 5

Sven

Attached section 5 – the HLC version – as modified by the TA you sent us on the SLC version (we too are annoyed and tired –sorry about the parallel tracking here.). we'd like your review of this before we send it to the House. Section 6 will follow likely around mid-day. Rapid turnaround appreciated.

Thanks
Michal

[DISCUSSION DRAFT]

SEC. ❚❚. MANUFACTURING AND PROCESSING NOTICES.

Section 5 of the Toxic Substances Control Act (15 U.S.C. 2604) is amended—

(1) in subsection (a)—

(A) in paragraph (1)—

(i) by striking "Except as provided in" and inserting "(A) Except as provided in subparagraph (B) of this paragraph and";

(ii) by redesignating subparagraphs (A) and (B) as clauses (i) and (ii), respectively;

(iii) by striking all that follows "significant new use;" ~~and all that follows~~ and inserting a period; and

(iv) by adding at the end the following:

"(B) A person may take the actions described in subparagraph (A) if—

"(i) such person submits to the Administrator, at least 90 days before such manufacture or processing, a notice, in accordance with

subsection (d), of such person's intention to manufacture or process such substance and such person complies with any applicable requirement of or imposed under subsection (b), (e), or (f); and

"(ii) the Administrator conducts a review of the notice and either—

"(I) makes a determination under paragraph (3)(A) and, as necessary, issues an order ~~to restrict such manufacturing or processing~~ under subsection (f)(1); or

"(II) makes a determination under paragraph (3)(B) and issues an order under subsection (e)(1)(B).''; and

(B) by adding at the end the following new paragraphs:

"(3) REVIEW AND DETERMINATION.—Before the end of the applicable review period, which shall be the 90-day period for review under paragraph (1), subject to any extensions made pursuant to subsection (b), (c) or (e), and subject to section 18, the Administrator shall review a notice received under paragraph (1) and—

"(A) determine whether the relevant chemical substance or significant new use may present an unreasonable risk of injury to health

Commented [A1]: EPA TA: Suggest dropping "made", since the only extension allowed under under (b) happens by operation of statute.

or the environment, without consideration of

costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use, and take applicable action under subsection (f) or (g); or

"(B) determine that additional information is necessary to make the determination under subparagraph (A), and take applicable action under subsection (e).

"(4) FAILURE TO RENDER DETERMINATION.—

"(A) IN GENERAL.—The Administrator shall complete a review of a notice required by this section within the applicable review period ~~provided in subsections (a) and (c)~~.

"(B) FAILURE TO RENDER DETERMINATION.—If the Administrator fails to make a determination on a notice under paragraph (3) by the end of the applicable review period~~, including an extension pursuant to subsection (c) or (e)(1)(A)(ii)~~, and the notice has not been withdrawn by the submitter, the Administrator shall refund to the submitter all applicable fees charged to the submitter for review of the notice pursuant to section 26(b)(1), and the Ad-

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ministrator shall not be relieved of any requirement to make such determination.

"(C) LIMITATIONS.—(i) A refund of applicable fees under subparagraph (B) shall not be made if the Administrator certifies that the submitter has not provided information required under subsections (b) or (e) or has otherwise unduly delayed the process such that the Administrator is unable to render a determination within the applicable period of review.

"(ii) A failure of the Administrator to render a decision shall not be deemed to constitute a withdrawal of the notice.

"(iii) Nothing in this paragraph shall be construed as relieving the Administrator or the submitter of the notice from any requirement of this section.

"(5) ARTICLE CONSIDERATION.—The Administrator may require notification under this section for the import or processing of a chemical substance as part of an article or category of articles under paragraph (1)(B) if the Administrator makes an affirmative finding in a rule under paragraph (2) that the reasonable potential for exposure to the chemical

substance through the article or category of articles subject to the rule justifies notification.";

(2) in subsection (b)—

(A) in the subsection heading, by striking "TEST DATA" and inserting "INFORMATION";

(B) in paragraph (1)—

(i) in subparagraph (A)—

(I) by striking "test data" and inserting "information"; and

(II) by striking "such data" and inserting "such information"; and

(ii) in subparagraph (B), by striking "test data" and inserting "information";

(C) in paragraph (2)—

(i) in subparagraph (A)—

(I) by striking "test data" and inserting "information";

(II) by striking "shall" and inserting "may"; and

(III) by striking "data prescribed" and inserting "information prescribed"; and

(ii) in subparagraph (B)—

(I) by striking "Data" and inserting "Information";

Commented [A2]: Insert:
(i) in subparagraph (A)—
(I) by striking "rule promulgated" and inserting "rule, order, or consent agreement"; and
(II) by inserting ", order, or consent agreement" after "such rule";
(ii) in subparagraph (B)(ii), by striking "promulgated" and inserting "or order"; and
(iii) in the undesignated matter at the end—
(I) by inserting "or order" after "such rule";

Commented [A3]: Insert:
(i) in subparagraph (A)—
(I) in clause (ii), by striking "rule promulgated" and inserting "rule, order, or consent agreement"; and

(II) by striking "data" both places it appears and inserting "information"; and

(III) by striking "show" and inserting "shows";

(D) in paragraph (3)—

(i) by striking "Data" and inserting "Information"; and

(ii) by striking "paragraph (1) or (2)" and inserting "paragraph (1) or (2) of this subsection or under subsection (e)"; and

(E) in paragraph (4)—

(i) in subparagraph (A)(i), by inserting ", without consideration of costs or other nonrisk factors" after "health or the environment"; and

(ii) in subparagraph (C), by striking ", except that" and all that follows through "subparagraph (A)";

(3) in subsection (c)—

(A) in the subsection heading, by inserting "AND REVIEW" after "NOTICE"; and

(B) by striking "before which" and all that follows through "subsection may begin";

(4) in subsection (d)—

(A) by striking "test data" in paragraph (1)(B) and inserting "information";

(B) by striking "data" each place it appears in paragraph (1)(C) and paragraph (2) and inserting "information";

(C) in paragraph (2)(B), by striking "uses or intended uses of such substance" and inserting "uses of such substance identified in the notice and any additional uses of such substance that are reasonably foreseeable by the Administrator"; and

Commented [A4]: Insert:
(D) in paragraph (2)(C), by inserting ", order, or consent agreement" after "rule"

(D) by striking "notification" both places it appears in paragraph (3);

(E) in paragraph (3), by striking "for which the period prescribed by subsection (a), (b), or (c)" and inserting "and for which the applicable review period"

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(5) by amending subsection (e) to read as follows:

"(e) REGULATION WHEN AVAILABLE INFORMATION IS INSUFFICIENT.—(1) If the Administrator determines that the information available to the Administrator is insufficient to permit the Administrator to make a determination in accordance with subsection (a)(3)(A) for a chemical substance or significant new use with respect to which notice is required by subsection (a)—

"(A) the Administrator—

"(i) shall provide an opportunity for the submitter of the notice to submit the additional information within the applicable review period;

"(ii) may, by agreement with the submitter, extend the review period for a reasonable time to allow the development and submission of the additional information;

"(iii) may extend the applicable review period as necessary and promulgate a rule, enter into a consent agreement, or issue an order under section 4 to require the development of the information; and

Commented [A5]: EPA TA: You have "applicable" here but not in ii or iv. Seems like either way is ok in this context, but should be consistent.

"(iv) on receipt of the additional information the Administrator finds supports the determination under subsection (a)(3)(A), which shall automatically extend the review period for 90 days, shall make the determination within 90 days of receipt of the information; and

"(B) the Administrator may issue an order to take effect on the expiration of the applicable ~~notification and~~ review period ~~under subsection (a), (b), or (c)~~ to prohibit or otherwise restrict the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance, or manufacture or processing of the chemical substance for a significant new use, or any combination of such activities,

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2523 sufficient to allay the Administrator's initial concern

that, in the absence of sufficient information, the substance or significant new use may present an unreasonable risk of injury to health or the environment.

"(2) In selecting among prohibitions and other restrictions to include in an order to be issued by the Administrator to meet the standard under paragraph (1), the Administrator shall consider, to the extent practicable based on reasonably available information, costs and other nonrisk factors.

"(3) If the Administrator issues an order under paragraph (1), the submitter of the notice under subsection (a) may commence manufacture of the chemical substance, or manufacture or processing of the chemical substance for a significant new use, pursuant to this subsection only in compliance with the restrictions specified in the order.

"(4) Not later than 90 days after issuing an order under paragraph (1), the Administrator shall consider whether to promulgate a rule pursuant to subsection (a)(2) that identifies as a significant new use any manufacturing, processing, use, distribution in commerce, or disposal of the chemical substance that does not conform to the restrictions imposed by the order, and, as applicable, initiate such a rulemaking or publish a statement de-

scribing the reasons of the Administrator for not initiating such a rulemaking.

"(5) An order may not be issued under paragraph (1) respecting a chemical substance—

"(A) later than 45 days before the expiration of the notification period applicable to the manufacture or processing of such substance under subsection (a), (b), or (c); and

"(B) unless the Administrator has, on or before the issuance of the order, notified, in writing, each manufacturer or processor, as the case may be, of such substance of the determination which underlies such order.";

(6) by amending subsection (f) to read as follows:

"(f) PROTECTION AGAINST POTENTIAL UNREASONABLE RISKS.—

"(1) ORDERS.—If the Administrator determines that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or a significant new use with respect to which notice is required by subsection (a), or that any combination of such activities, may present an unreasonable risk of injury to health or the environment in accordance with subsection (a)(3)(A)—

"(A) the Administrator shall issue an order, to take effect on or before the expiration of the applicable ~~notification and~~ review period ~~under subsection (a), (b), or (c)~~ to prohibit or otherwise restrict the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance, or of the chemical substance for a significant new use, sufficient to allay the Administrator's initial concern that the substance or significant new use may present an unreasonable risk of injury to health or the environment;

"(B) no person may commence manufacture of the chemical substance, or manufacture or processing of the chemical substance for a significant new use, pursuant to this subsection except in compliance with the restrictions specified in the order; and

"(C) not later than 90 days after issuing an order under subparagraph (A), the Administrator shall consider whether to promulgate a rule pursuant to subsection (a)(2) that identifies as a significant new use any manufacturing, processing, use, distribution in commerce, or disposal of the chemical substance

that does not conform to the restrictions imposed by the order, and, as applicable, initiate such a rulemaking or publish a statement describing the reasons of the Administrator for not initiating such a rulemaking.

"(2) SELECTING PROHIBITIONS AND RESTRICTIONS.—In selecting among prohibitions and other restrictions to include in an order to be issued by the Administrator to meet the standard under paragraph (1), the Administrator shall, to the extent practicable based on reasonably available information, consider costs and other nonrisk factors, and such an order may include—

"(A) a requirement limiting the amount of the chemical substance which may be manufactured, processed, or distributed in commerce;

"(B) a requirement described in paragraph (2), (3), (4), (5), (6), or (7) of section 6(a); or

"(C) any combination of the requirements referred to in subparagraph (B).

"(3) PERSISTENT AND BIOACCUMULATIVE SUBSTANCES.—For a chemical substance that is subject to the requirements of this subsection and that the Administrator determines, with respect to persistence and bioaccumulation, scores high for 1 and ei-

Commented [A6]: EPA TA: Picky point, but the word "consider" appears after "the Administrator shall" in (e).

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ther high or moderate for the other, pursuant to the TSCA Work Plan Chemicals Methods Document published by the Administrator in February 2012 (or a successor scoring system), the Administrator shall, in selecting among prohibitions and other restrictions to include in an order to be issued by the Administrator to meet the standard under paragraph (1), reduce the potential for exposure to the substance to the maximum extent practicable.

"(4) WORKPLACE EXPOSURES.—To the extent practicable, the Administrator shall consult with the Assistant Secretary of Labor for Occupational Safety and Health prior to adopting any prohibition or other restriction under this subsection to address workplace exposures.";

(7) by amending subsection (g) to read as follows:

"(g) STATEMENT ON ADMINISTRATOR FINDING.—If the Administrator finds, in accordance with subsection (a)(3)(A), that a determination that the relevant chemical substance or significant new use may present an unreasonable risk of injury to health or the environment is not warranted, then notwithstanding any remaining portion of the applicable review period ~~for review under subsection (a), (b), or (c) applicable to the manufacturing or processing of such substance~~

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~~or of such substance for a significant new use~~, the submitter of the notice may commence manufacture for commercial purposes of the chemical substance or manufacture or processing of the chemical substance for commercial purposes for a significant new use, and the Administrator shall make public a statement of the Administrator's finding. Such a statement shall be submitted for publication in the Federal Register as soon as is practicable before the expiration of such period. Publication of such statement in accordance with the preceding sentence is not a prerequisite to the manufacturing or processing of the substance with respect to which the statement is to be published.";

(8) in subsection (h)—

(A) in paragraph (1)(A), by inserting ", including an unreasonable risk to a potentially exposed or susceptible subpopulation identified by the Administrator for the specific uses identified in the application" after "health or the environment";

(B) in paragraph (2), by striking "data" each place it appears and inserting "information"; and

(C) in paragraph (4), by striking ". A rule promulgated" and all that follows through "section 6(c)" and inserting ", without consider-

Commented [A7]: EPA TA: Picky point, but this phrase appears "of the chemical substance" in the preceding line.

Commented [A8]: EPA TA: Confirming that you are intending to allow the consideration of cost and non-risk factors here, while disallowing it under 5(h)(4).

Commented [A9]: Insert:
(B) in paragraph (1)(B), by striking "appropriate" and inserting "warranted";

ation of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified by the Administrator under the conditions of use"; and

(9) by amending subsection (i) to read as follows:

"(i) DEFINITIONS.—(1) For purposes of this section, the terms 'manufacture' and 'process' mean manufacturing or processing for commercial purposes.

"(2) For purposes of this Act, the term 'requirement' as used in this section shall not displace any statutory or common law.".

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/8/2016 8:41:37 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Re: Sen. Markey TSCA TA request on section 26

Michal- got it. We'll get you TA on sect. 26 before 1pm tomorrow. Thanks,
Sven

On Apr 8, 2016, at 4:36 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

We are meeting at 1 pm tomorrow. Before then?

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey
<image001.png><image002.png><image003.png><image004.jpg>

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Friday, April 08, 2016 4:35 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA request on section 26

Michal, How quick on 26, tomorrow okay? Thanks,
Sven

On Apr 8, 2016, at 3:18 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Can you pls turn this around quickly? Not tons of changes from last time you saw it, but includes a lot of the feedback you provided before.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
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255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey
<image001.png><image002.png><image003.png><image004.jpg>

<sec26_01_xml.pdf>

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 2/24/2016 5:11:17 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TA request - section 4/5 nexus

Michal,
This responds to your TA request on section 4/5 nexus.

The bill does not specify that a test order or rule, issued solely because it was necessary to review a PMN notice, would cease to have effect if the PMN were later withdrawn. Therefore, such an order/rule would not necessarily and immediately cease to have legal effect under such circumstances.

However, EPA already has sufficient authority under the bill to incorporate a contingency provision into the test order or rule, whereby that order/rule would automatically expire if the PMN were withdrawn. Even if EPA elected not to include such a provision, the withdrawal of the PMN would mean that EPA would have no rational basis to refuse a request to correspondingly withdraw the test rule/order (i.e., assuming that no other grounds for the testing had since become apparent).

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, February 23, 2016 1:44 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: TA request - section 4/5 nexus

Sven

In section 4, epa can issue test orders for purposes of reviewing a PMN. In section 5, we say that PMNS can be withdrawn. What if the PMN is withdrawn before the testing is completed - what happens to the test order? Do we need to build in a withdrawal of the test order into section 5 for that circumstance?

Thanks
Michal

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/3/2016 12:13:25 AM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Re: Sen. Markey TSCA TA request on House fees language and 25% cap

Michal, we're on it. I talked to Jim Jones and the OGC attorneys and we can get TA out tomorrow. We'll prioritize based on your last note. Please let me know if any updates. Thanks,
Sven

On Apr 2, 2016, at 8:02 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Thanks. Just got the revised "hurry up".

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

From: Kaiser, Sven-Erik
Sent: Saturday, April 2, 2016 7:49 PM
To: Freedhoff, Michal (Markey)
Subject: Re: Sen. Markey TSCA TA request on House fees language and 25% cap

Ok- will tell folks.

On Apr 2, 2016, at 7:30 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Sven, I need to rearrange these priorities if possible

Can we get TA on the 26 draft from the House (just the fees and partial RES if you're drafting that to 26) TOMORROW at earliest possible opportunity? We'd also like Dimitri's section 19 TA for tomorrow.

There is a desire to send the House new Senate 4 and 14 and comments on House 8, 26, 16, 19 tomorrow. I am saying no to 26 until we get your input, but we need it asap.

5 will be next priority and desire is to send that to House Monday. I'm saying no until we get your input but really need your input asap.

Thanks
Michal

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

From: Kaiser, Sven-Erik
Sent: Saturday, April 2, 2016 12:54 PM
To: Freedhoff, Michal (Markey)
Subject: Re: Sen. Markey TSCA TA request on House fees language and 25% cap

Michal, thanks for the priorities and the heads up on the coming week. Best,
Sven

On Apr 2, 2016, at 12:32 PM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Thanks! do you have a sense for when we will get 5 back? Since we anticipate having to make changes to address TA we are really hoping we get it early in the day, and think some specific TA on 26 text should follow that in terms of your priorities. We have sent your earlier TA on prior risk evaluations for 26 to the House before, but the message is not getting through for some reason (I don't believe intentional) as you'll see from the 26 text. If you're planning on sending me partial RE text to go into this section, it would be VERY helpful to get that asap on Monday as well so we can send it back in a Senate counter.

Finally, generally speaking, I anticipate more time crunch this week and hope you can let your team know that we will probably be pushing for fast turnaround on many things.

Thanks very much
M

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

From: Kaiser, Sven-Erik
Sent: Saturday, April 2, 2016 8:49 AM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA request on House fees language and 25% cap

Michal- TA on House fees. Please let me know if any questions. Thanks,
Sven
Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

House included the language we worked thru together that will enable funds to be used for risk management and cbi associated with the substance in question, which obviously addresses a main limitation in the House-passed bill.

How does that intersect with the senate's 25% fee cap - if fees can only be used on the chemical substance for which the fee is assessed, how does that intersect with epa's other tsca activities - like the broader cbi authorities for example? Can both the new House provision and the 25% language co-exist without unintended problems?

Response: We do not see a conceptual impediment as the relationship would presumably be similar to the one that exists already in the Senate offer between the cap and EPA's authority to use the fees on other activities, albeit with a restriction on the chemical by chemical use. However, we would need to see statutory language attempting to meld the possible provision with the a cap to have a more informed judgement regarding possible issues arising from their interaction.

From: "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>

Date: March 25, 2016 at 7:02:33 AM EDT
To: "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov>
Subject: Specific question on fees language sent yesterday

House included the language we worked thru together that will enable funds to be used for risk management and cbi associated with the substance in question, which obviously addresses a main limitation in the House-passed bill.

How does that intersect with the senate's 25% fee cap - if fees can only be used on the chemical substance for which the fee is assessed, how does that intersect with epa's other tsca activities - like the broader cbi authorities for example? Can both the new House provision and the 25% language co-exist without unintended problems?

Thx

M

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/29/2016 12:55:05 AM
To: Couri, Jerry [JerryCouri@mail.house.gov]
Subject: Re: TA request on TSCA section 5
Attachments: HEC.TSCA TA.sec 5 of House (4-22).docx; ATT00001.htm; HEC.TSCA TA.section 5(e) and (f).docx; ATT00002.htm

Jerry,
This TA responds to the request on section 5(e).

We sent suggested changes both to the new 5(a)(3)(B) (to align with 5(e)) and to 5(e)(1)(A) (e.g., to remove the language about substantial production, release and exposure, which is not part of the 5(a)(3)(B) finding under your draft). Do you have specific questions about the changes we suggested to the lead in to 5(e)? See attachments for the most recent section 5 TA.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any additional questions. Thanks,

Sven

Sven-Erik Kaiser

U.S. EPA

Office of Congressional and Intergovernmental Relations

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On Apr 28, 2016, at 5:53 PM, Couri, Jerry <JerryCouri@mail.house.gov> wrote:

Sven:

Thanks to you and the folks at EPA for the TA on section 5. We have a follow-up question on what you sent to us:

If we change the wording in proposed new section 5(a)(3)(B) to match existing section 5(e) -- as I think the Agency's TA suggests, would we need to change the lead in to existing 5(e)?

Thanks.

- <!--[if !supportLists]--><!--[endif]-->Jerry

Gerald S. Couri
Senior Environmental Policy Advisor | Committee on Energy and Commerce
U.S. House of Representatives
2125 Rayburn Building | 202.226.9603 (direct)

SEC. 5. MANUFACTURING AND PROCESSING NOTICES.

Section 5 of the Toxic Substances Control Act (15 U.S.C. 2604) is amended—

(1) in subsection (a)—

(A) in paragraph (1)—

(i) by striking "Except as provided in" and inserting "(A) Except as provided in subparagraph (B) of this paragraph and";

(ii) by redesignating subparagraphs (A) and (B) as clauses (i) and (ii), respectively;

(iii) by striking all that follows "significant new use" and inserting a period; and

(iv) by adding at the end the following:

"(B) A person may take the actions described in subparagraph (A) if—

"(i) such person submits to the Administrator, at least 90 days before such manufacture or processing, a notice, in accordance with subsection (d), of such person's intention to manufacture or process such substance and such person complies with any applicable requirement imposed under subsection (a), (b), (e), or (f); and

"(ii) the Administrator—

"(I) conducts a review of the notice; and

"(II) makes a determination under subparagraph (A), (B), (C), or (D), ~~or (E)~~ of paragraph (3) and takes the actions required in association with that determination under such subparagraph."; and

(B) by adding at the end the following new paragraphs:

"(3) REVIEW AND DETERMINATION.—Not later than 90 days after receipt of a notice under paragraph (1), subject to section 18, the Administrator shall review such notice and determine—

"(A) that the relevant chemical substance or significant new use presents or will present an unreasonable risk of injury to health or the

Commented [A1]: (a)(3) imposes important applicable requirements.

environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use, in which case the Administrator shall take ~~applicable~~ the actions required under subsection (f);

~~"(B) that the relevant chemical substance or significant new use is likely to present an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use, in which case the Administrator shall~~

~~"(i) by consent agreement or order, prohibit or otherwise restrict the manufacture, processing, use, distribution in commerce, or disposal (as applicable) of the chemical substance, or of the chemical substance for a significant new use, such that the Administrator determines that compliance with such prohibition or restrictions is sufficient to ensure that the chemical~~

Commented [A2]: In our suggested revision to (f), it would retain two procedural options (rule or order), but the choice of which option to take would be at the Administrator's discretion. So "applicable" does not seem appropriate, because either would be applicable.

~~substance or significant new use is not likely to present an unreasonable risk of injury to health or the environment; and~~

~~"(ii) take applicable action under paragraphs (4) through (8) of subsection (f);~~

"(B~~C~~) that information available to the Administrator is insufficient to permit a reasoned evaluation of the health and environmental effects of the relevant chemical substance or significant new use, and in the absence of such information, the chemical substance or significant new use may present an unreasonable risk of injury to health or the environment, without consideration of costs, or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use, in which case the Administrator shall take ~~applicable~~ the actions required under subsection (e);

"(C~~D~~) that the relevant chemical substance or significant new use is likely not to present an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Ad-

Commented [A3]: This provision is stricken because (B) is stricken. But this raises the question whether the requirements of 4-8 should apply to (e) orders as well as (f) orders – both because some of the chemicals that would have been subject to this special order provision under (B) will now be subject to (e), and also because logically it appears that at least some of these provisions should apply to (e) as well. See comments on these provisions of (f), below.

Commented [A4]: A stray comma that does not appear in other places where this phrase is used.

Commented [A5]: We suggest, below, amending (e) so that the only available action is issuance of an order. So "applicable" would make no sense.

ministrator under the conditions of use, in which case the Administrator shall publish such

determination and the submitter of the notice may commence manufacture of the chemical substance or manufacture or processing for a significant new use; or

"(DE) that the relevant chemical substance is a low-hazard substance, in which case the Administrator shall publish such determination and the submitter of the notice may commence manufacture of the chemical substance or manufacture or processing ~~processing of the chemical substance~~for a significant new use.

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Commented [A6]: To conform to wording in (C).

"(4) FAILURE TO RENDER DETERMINATION.—

"(A) FAILURE TO RENDER DETERMINATION.—If the Administrator fails to make a determination on a notice under paragraph (3) by the end of the applicable review period and the notice has not been withdrawn by the submitter, the Administrator shall refund to the submitter all applicable fees charged to the submitter for review of the notice pursuant to section 26(b)(1), and the Administrator shall not be relieved of any requirement to make such determination.

"(B) LIMITATIONS.—(i) A refund of applicable fees under subparagraph (A) shall not be made if the Administrator certifies that the

submitter has not provided information required under subsection (b) ~~or (c)~~ or has otherwise unduly delayed the process such that the Administrator is unable to render a determination within the applicable period of review.

"(ii) A failure of the Administrator to render a decision shall not be deemed to constitute a withdrawal of the notice.

"(iii) Nothing in this paragraph shall be construed as relieving the Administrator or the submitter of the notice from any requirement of this section.

"(5) ARTICLE CONSIDERATION.—In promulgating a rule under paragraph (2), the Administrator shall consider whether there is a likely potential for exposure to a chemical substance through an article or category of articles, and if the Administrator finds such a likely potential, the Administrator shall require notification under this section for the import or processing of a chemical substance as part of the article or category of articles.";

(2) in subsection (b)—

(A) in the subsection heading, by striking "TEST DATA" and inserting "INFORMATION";

(B) in paragraph (1)—

Commented [A7]: (e) does not provide for submission of information in this draft, and in any event any submission of information under an (e) order would occur after the close of the review period.

Commented [A8]: Suggest replacing "this section" with "paragraph (1)(A)(ii)". This paragraph (5) as far as we can tell relates only to significant new uses, not to new chemicals, so the reference to the provision under which notification is required should be to the significant new use provision only.

Commented [A9]: (b) revisions not reviewed – as far as we know (b) would not be impacted by the changes to a, e and f, but, again, have not reviewed.

(i) in subparagraph (A)—

(I) by striking "test data" and inserting "information"; and

(II) by striking "such data" and inserting "such information"; and

(ii) in subparagraph (B)—

(I) by striking "test data" and inserting "information";

(II) by striking "subsection (a)(1)(A)" and inserting "subsection (a)(1)(A)(i)"; and

(III) by striking "subsection (a)(1)(B)" and inserting "subsection (a)(1)(A)(ii)";

(C) in paragraph (2)—

(i) in subparagraph (A)—

(I) by striking "test data" in clause (ii) and inserting "information";

(II) by striking "shall" and inserting "may"; and

(III) by striking "data prescribed" and inserting "information prescribed"; and

(ii) in subparagraph (B)—

(I) by striking "Data" and inserting "Information";

(II) by striking "data" both places it appears and inserting "information";

(III) by striking "show" and inserting "shows";

(IV) by striking "subsection (a)(1)(A)" in clause (i) and inserting "subsection (a)(1)(A)(i)"; and

(V) by striking "subsection (a)(1)(B)" in clause (ii) and inserting "subsection (a)(1)(A)(ii)";

(D) in paragraph (3)—

(i) by striking "Data" and inserting "Information"; and

(ii) by striking "paragraph (1) or (2)" and inserting "paragraph (1) or (2) of this subsection or under subsection (e)"; and

(E) in paragraph (4)—

(i) in subparagraph (A)(i), by inserting ", without consideration of costs or other nonrisk factors" after "health or the environment"; and

(ii) in subparagraph (C), by striking ", except that" and all that follows through "subparagraph (A)";

(3) in subsection (c)—

(A) in the subsection heading, by striking "NOTICE" AND inserting "AND REVIEW" after "NOTICE"; and

Commented [A10]: Conforms to terminology used in section

(B) by striking "before which" and all that follows through "subsection may begin";

(4) in subsection (d)—

Commented [A11]: (d) revisions not reviewed.

(A) by striking "test data" in paragraph (1)(B) and inserting "information";

(B) by striking "data" each place it appears in paragraph (1)(C) and paragraph (2) and inserting "information";

(C) in paragraph (2)(B), by striking "uses or intended uses of such substance" and inserting "uses of such substance identified in the notice and any additional uses of such substance that are reasonably foreseeable by the Administrator"; and

(D) in paragraph (3)—

(i) by striking "for which the notification period prescribed by subsection (a), (b), or (c)" and inserting "for which the applicable review period"; and

(ii) by striking "such notification period" and inserting "such period";

~~(5) in subsection (e)(1)(A), by inserting "under subsection (a)(3)(C)" after "If the Administrator determines";~~

~~(6) in subsection (f)—~~

~~(A) in paragraph (2), by striking "section 6(d)(2)(B)" and inserting "section 6(e)(3)"; and~~

(B) by adding at the end the following:

"(4) PROHIBITION.—If the Administrator makes a determination under subsection (a)(3)(A) ~~or~~ (B) with respect to a chemical substance or a significant new use, no person may commence manufacture of the chemical substance, or manufacture or processing of the chemical substance for a significant new use, pursuant to this subsection except in compliance with the restrictions specified in a rule promulgated under paragraph (2).

"(5) TREATMENT OF NONCONFORMING USES.—Not later than 90 days after taking an action under paragraph (2) or (3) relating to a chemical substance with respect to which the Administrator has made a determination under subsection (a)(3)(A) ~~or~~ (B), the Administrator shall consider whether to

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Commented [A12]: See suggested changes to 5(e)

Commented [A13]: See suggested edits in 5(f). Also, based on drafts we have seen, we would think the correct citation would be 6(d)(2)(C).

Commented [A14]: This is unnecessary, because (a) already prohibits manufacturing and processing without an f order if EPA has made the finding under (A) (although, see suggested changes to (a) above to make this clearer). Also, since there is no comparable provision under (e), this could suggest that manufacturing out of compliance with an (e) order as acceptable. (Also, this text references only rules under paragraph (2), but paragraph (2) also provides for orders). Suggest dropping.

Commented [A15]: For 5-8, we think it probably makes sense to have these requirements also apply to (e) orders. For (5) in particular, it is not clear why EPA would be told to consider a SNUR following an f order but not an e order. EPA currently routinely considers SNURs following e orders.

Thus, we suggest adding them to (e), with necessary modifications. They would have to be modified to reference a determination under a3B rather thana3A, and see additional modification suggestions below.

promulgate a rule pursuant to subsection (a)(2) that identifies as a significant new use any manufacturing, processing, use, distribution in commerce, or disposal of the chemical substance that does not conform to the restrictions imposed by the order, and, as applicable, initiate such a rulemaking or publish a statement describing the reasons of the Administrator for not initiating such a rulemaking.

"(6) SELECTING PROHIBITIONS AND RESTRICTIONS.—In selecting among prohibitions and other restrictions, relating to a chemical substance with respect to which the Administrator has made a determination under subsection (a)(3)(A) ~~or (B)~~, to include in an order to be issued by the Administrator to meet the standard under paragraph (1), the Administrator shall consider, to the extent practicable based on reasonably available information, costs and other nonrisk factors~~, and such an order shall include a requirement described in section 6(a)~~.

"(7) PERSISTENT AND BIOACCUMULATIVE SUBSTANCES.—For a chemical substance with respect to which the Administrator has made a determination under subsection (a)(3)(A) ~~or (B)~~ that the Administrator determines, with respect to persistence and bioaccumulation, scores high for 1 and either high or

Commented [A16]: If this provision (6) is copied into (e), an issue is raised as to how to preserve this concept. This phrase would not make sense under (e), since (e) does not provide an explicit standard. On the other hand, issues would be created by deleting the phrase in the (e) version of (6), because EPA would then be instructed to consider costs and other nonrisk factors with no direction to consider or address the risk. A solution to this would be to add, at the end of (e)(1), "to the extent necessary to address the Administrator's risk concerns", which would provide a standard for (e). This language parallels the (f) standard currently in TSCA ("to the extent necessary to protect against such risk") , as modified to account for the lack of an affirmative risk finding. If that were added, the highlighted phrase here could be included in the (e) version of (6).

Commented [A17]: (f) (2) and (3) already incorporate the 6(a) requirements, so this is redundant at best and confusing because it suggests EPA can include any requirements it chooses so long as they include a 6(a) requirement.

moderate for the other, pursuant to the TSCA Work Plan Chemicals Methods Document published by the Administrator in February 2012 (or a successor scoring system), the Administrator shall, in selecting among prohibitions and other restrictions to include in an order to be issued by the Administrator to meet the standard under paragraph (1), reduce the potential for exposure to the substance to the extent practicable.

"(8) WORKPLACE EXPOSURES.—To the extent practicable, the Administrator shall consult with the Assistant Secretary of Labor for Occupational Safety and Health prior to adopting any prohibition or other restriction relating to a chemical substance with respect to which the Administrator has made a determination under subsection (a)(3)(A) ~~or (B)~~ to address workplace exposures.";

(7) by amending subsection (g) to read as follows:

"(g) STATEMENT ON ADMINISTRATOR FINDING.—If the Administrator finds, in accordance with subsection (a)(3)(D), that a chemical substance or significant new use is likely not to present an unreasonable risk of injury to health or the environment, then notwithstanding any remaining portion of the applicable review period, the sub-

Commented [A18]: Per comment on (6) above, if this is added to (e), the highlighted phrase will not make sense unless a standard is added to (e).

Commented [A19]: (g) not reviewed

mitter of the notice may commence manufacture of the chemical substance or manufacture or processing for a significant new use, and the Administrator shall make public a statement of the Administrator's finding. Such a statement shall be submitted for publication in the Federal Register as soon as is practicable before the expiration of such period. Publication of such statement in accordance with the preceding sentence is not a prerequisite to the manufacturing or processing of the substance with respect to which the statement is to be published.";

(8) in subsection (h)—

Commented [A20]: (h) not reviewed

(A) in paragraph (1)(A), by inserting ", including an unreasonable risk to a potentially exposed or susceptible subpopulation identified by the Administrator for the specific uses identified in the application" after "health or the environment";

(B) in paragraph (2), by striking "data" each place it appears and inserting "information"; and

(C) in paragraph (4), by striking ". A rule promulgated" and all that follows through "section 6(c)" and inserting ", including an unreasonable risk to a potentially exposed or suscep-

tible subpopulation identified by the Administrator under the conditions of use"; and

(9) by amending subsection (i) to read as follows:

"(i) DEFINITIONS.—(1) For purposes of this section, the terms 'manufacture' and 'process' mean manufacturing or processing for commercial purposes.

"(2) For purposes of this Act, the term 'requirement' as used in this section shall not displace any statutory or common law.

"(3) For purposes of this section, the term 'applicable review period' means the period starting on the date the Administrator receives a notice under subsection (a)(1) and ending 90 days after that date, or on such later date as is provided for in subsection (l) or provided for in an extension under subparagraph (C) on the date the Administrator makes a determination under subsection (a)(3), as extended pursuant to subsection (e) or (e)(1)(A).".

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Commented [A21]: Two issues with this as worded. 1. It is confusing to say the period ends when EPA makes a determination. That suggests that if EPA fails to make a determination in the required timeframe, the period is automatically extended, indefinitely. Is that the intent? 2. (e)(1)(A) does not provide for extensions.

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

§ 2604. Manufacturing and processing notices

(e) Regulation pending development of information.

(1) (A) If the Administrator determines that--

(i) the information available to the Administrator is insufficient to permit a reasoned evaluation of the health and environmental effects of a chemical substance with respect to which notice is required by subsection (a); and

(ii) ~~(I)~~ in the absence of sufficient information to permit the Administrator to make such an evaluation, ~~the manufacture, processing, distribution in commerce, use, or disposal of~~ such substance~~, or any combination of such activities,~~ may present an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use, ~~or~~

~~(II) such substance is or will be produced in substantial quantities, and such substance either enters or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure to the substance,~~

the Administrator ~~shall~~may issue an ~~proposed~~ order, to take effect on the expiration of the applicable review~~notification~~ period ~~applicable to the manufacturing or processing of such substance under subsection (a), (b), or (c)~~, to prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of such substance or to prohibit or limit any combination of such activities.

(B) An ~~proposed~~ order may not be issued under subparagraph (A) respecting a chemical substance (i) later than 45 days before the expiration of the applicable review~~notification~~ period ~~applicable to the manufacture or processing of such substance under subsection (a), (b), or (c)~~, and (ii) unless the Administrator has, on or before the issuance of the ~~proposed~~ order, notified, in writing, each manufacturer or processor, as the case may be, of such substance of the determination which underlies such order.

~~(C) If a manufacturer or processor of a chemical substance to be subject to a proposed order issued under subparagraph (A) files with the Administrator (within the 30-day period beginning on the date such manufacturer or processor received the notice required by subparagraph (B)(ii)) objections specifying with particularity the provisions of the order deemed objectionable and stating the grounds therefor, the proposed order shall not take effect.~~

~~(2) (A) (i) Except as provided in clause (ii), if with respect to a chemical substance with respect to which notice is required by subsection (a), the Administrator makes the determination described in paragraph (1)(A) and if—~~

~~(I) the Administrator does not issue a proposed order under paragraph (1) respecting such substance, or~~

~~(II) the Administrator issues such an order respecting such substance but such order does not take effect because objections were filed under paragraph (1)(C) with respect to it,~~

~~the Administrator, through attorneys of the Environmental Protection Agency, shall apply to the United States District Court for the District of Columbia or the United States district court for the judicial district in which the manufacturer or processor, as the case may be, of such substance is found, resides, or transacts business for an injunction to prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of~~

Commented [A1]: Changes to conform to wording of (a)(3)(B). Alternatively, the wording of a3B could change, but for the most part the bill seems to refer to the chemical itself presenting (or "may presenting") and unreasonable risk.

Commented [A2]: Again, conforming changes

Commented [A3]: Current TSCA says "may". But EPA *must* act under 5(e) – the "may" is only because EPA has the choice of issuing the order or initiating a court action to seek an injunction. The latter route does not seem like a good fit under the revised section 5, since the submitter is barred from manufacture/processing until EPA takes action under (e), and it seem counter-intuitive that a judicial filing by EPA seeking an injunction would be the EPA action that allows manufacture/processing to commence. Thus we have suggested striking the judicial route.

Commented [A4]: The order would no longer be merely proposed, because we suggest deleting the provisions that would void the order upon the filing of objections. The order would be a final EPA order, subject to judicial review.

Commented [A5]: Per TA on new section 5(f) provisions in the accompanying document, consider adding "to the extent necessary to address the Administrator's risk concerns" here, to provide a substantive standard for (e) orders.

Commented [A6]: We have retained this clause in the spirit of making fewer changes. Note though, that this is a protection for submitters in current TSCA, because it prevents EPA from issuing an order curtailing manufacture or processing late in the period, and that it arguably is not a good fit under the revised section 5, under which the submitter *needs* the order to proceed. If EPA misses this deadline, manufacture and processing would be barred under the revised section 5.

Commented [A7]: This is a large amount of stricken text, but per comments above, the judicial process does not seem like a good fit. Note that this does not leave the submitter without remedy. An EPA 5(e) order would be a final agency action subject to judicial review. Section 19 could be revised to provide for review in the courts of appeals, but revision to section 19 is not necessary to ensure review because, without such revision, these orders would be reviewable as final agency actions in district court under the APA.

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

~~such substance (or to prohibit or limit any combination of such activities).~~

~~(ii) If the Administrator issues a proposed order under paragraph (1)(A) respecting a chemical substance but such order does not take effect because objections have been filed under paragraph (1)(C) with respect to it, the Administrator is not required to apply for an injunction under clause (i) respecting such substance if the Administrator determines, on the basis of such objections, that the determinations under paragraph (1)(A) may not be made.~~

~~(B) A district court of the United States which receives an application under subparagraph (A)(i) for an injunction respecting a chemical substance shall issue such injunction if the court finds that—~~

~~(i) the information available to the Administrator is insufficient to permit a reasoned evaluation of the health and environmental effects of a chemical substance with respect to which notice is required by subsection (a); and~~

~~(ii) (I) in the absence of sufficient information to permit the Administrator to make such an evaluation, the manufacture, processing, distribution in commerce, use, or disposal of such substance, or any combination of such activities, may present an unreasonable risk of injury to health or the environment, or~~

~~(II) such substance is or will be produced in substantial quantities, and such substance either enters or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure to the substance.~~

~~(C) Pending the completion of a proceeding for the issuance of an injunction under subparagraph (B) respecting a chemical substance, the court may, upon application of the Administrator made through attorneys of the Environmental Protection Agency, issue a temporary restraining order or a preliminary injunction to prohibit the manufacture, processing, distribution in commerce, use, or disposal of such a substance (or any combination of such activities) if the court finds that the notification period applicable under subsection (a), (b), or (c) to the manufacturing or processing of such substance may expire before such proceeding can be completed.~~

~~(D) After the submission to the Administrator of test data sufficient to evaluate the health and environmental effects of a chemical substance subject to an injunction issued under subparagraph (B) and the evaluation of such data by the Administrator, the district court of the United States which issued such injunction shall, upon petition, dissolve the injunction unless the Administrator has initiated a proceeding for the issuance of a rule under section 6(a) [15 USCS § 2605(a)] respecting the substance. If such a proceeding has been initiated, such court shall continue the injunction in effect until the effective date of the rule promulgated in such proceeding or, if such proceeding is terminated without the promulgation of a rule, upon the termination of the proceeding, whichever occurs first.~~

(f) Protection against unreasonable risks.

(1) If the Administrator determines thatfinds that there is a reasonable basis to conclude that ~~the manufacture, processing, distribution in commerce, use, or disposal of a~~ a chemical substance or significant new use with respect to which notice is required by subsection (a), ~~or that any combination of such activities,~~ presents or will present an unreasonable risk of injury to health or environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use ~~before a rule promulgated under section 6 [15 USCS § 2605] can protect against such risk,~~ the

Commented [A8]: Changes to conform with wording in (a)(3)(A).

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Administrator shall, before the expiration of the applicable reviewnotification period ~~applicable under subsection (a), (b), or (c) to the manufacturing or processing of such substance~~, take the action authorized by paragraph (2) or (3) to the extent necessary to protect against such risk.

(2) The Administrator may issue a proposed rule under section 6(a) [15 USCS § 2605(a)] to apply to a chemical substance with respect to which a finding was made under paragraph (1)--

(A) a requirement limiting the amount of such substance which may be manufactured, processed, or distributed in commerce,

(B) a requirement described in paragraph (2), (3), (4), (5), (6), or (7) of section 6(a) [15 USCS § 2605(a)(2), (3), (4), (5), (6), or (7)], or

(C) any combination of the requirements referred to in subparagraph (B).

Such a proposed rule shall be effective upon its publication in the Federal Register. Section 6(d)(2)(B) [15 USCS § 2605(d)(2)(B)] shall apply with respect to such rule.

Commented [A9]: We think this is now 6(d)(3)(B).

(3) (A) The Administrator may--

~~(i)~~ issue an ~~proposed~~ order to prohibit or limit the manufacture, processing, or distribution in commerce of a substance with respect to which a finding was made under paragraph (1)~~, or~~

Commented [A10]: Current TSCA gives EPA two choices under 5(f): to issue a proposed rule under (2) to limit (but not prohibit) activities with the chemical, or to issue an order under (3) to prohibit (but not otherwise limit) the activities. Because it is probably not realistic for EPA to issue a proposed section 6(a) rule within the review period (and because 6(a) as worded in the bill does not recognize 5(f) as an "on ramp"), we believe that EPA is much more likely to act through the order authority and suggest giving EPA authority to limit via order. Otherwise, EPA's only option would be to prohibit.

~~(ii) apply, through attorneys of the Environmental Protection Agency, to the United States District Court for the District of Columbia or the United States district court for the judicial district in which the manufacturer, or processor, as the case may be, of such substance, is found, resides, or transacts business for an injunction to prohibit the manufacture, processing, or distribution in commerce of such substance.~~

~~A proposed~~ Such order ~~issued under clause (i) respecting a chemical substance~~ shall take effect on the expiration of the applicable review ~~notification~~ period ~~applicable under subsection (a), (b), or (c) to the manufacture or processing of such substance~~.

~~(B) If the district court of the United States to which an application has been made under subparagraph (A)(ii) finds that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance with respect to which such application was made, or that any combination of such activities, presents or will present an unreasonable risk of injury to health or the environment before a rule promulgated under section 6 [15 USCS § 2605] can protect against such risk, the court shall issue an injunction to prohibit the manufacture, processing, or distribution in commerce of such substance or to prohibit any combination of such activities.~~

(C) The provisions of subparagraphs (B) ~~and (C)~~ of subsection (e)(1) shall apply with respect to an order issued under ~~clause (i) of~~ subparagraph (A)~~, and the provisions of subparagraph (C) of subsection (e)(2) shall apply with respect to an injunction issued under subparagraph (B)~~.

Commented [A11]: (C) stricken because stricken in (e)(1). (B) retained but, per comment above, this is the provision requiring EPA to issue the order 45 days before expiration of period. If that provision is dropped from (e), then this entire subparagraph (C) should be dropped.

~~(D) If the Administrator issues an order pursuant to subparagraph (A)(i) respecting a chemical substance and objections are filed in accordance with subsection (e)(1)(C), the Administrator shall seek an injunction under subparagraph (A)(ii) respecting such substance unless the Administrator determines, on the basis of such objections, that such substance does not or will not present an unreasonable risk of injury to health or the environment.~~

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/11/2016 10:06:38 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TA Request on section 14
Attachments: Senate TA (as passed) - Section 14.docx

Michal,
This responds to your TA request on section 14. You already have our comprehensive TA on the Senate bill as passed including TA on section 14 - attached is a pullout from that on section 14. We didn't see anything major in the new draft, spotted some potential glitches and it needs conforming changes that we haven't had a chance to pull together. Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
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-----Original Message-----
From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Friday, March 11, 2016 4:37 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Re: TA support

Thanks. Those sections likely next week now. I think we are headed to 14 next - if you have TA on House 14 prepared pls send.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations Office of Senator Edward J. Markey (D-MA)
Original Message

SEC. 14. CONFIDENTIAL INFORMATION.

Section 14 of the Toxic Substances Control Act (15 U.S.C. 2613) is amended to read as follows:

"SEC. 14. CONFIDENTIAL INFORMATION.

"(a) In General.—Except as otherwise provided in this section, the Administrator shall not disclose information that is exempt from disclosure pursuant to subsection (a) of section 552 of title 5, United States Code, under subsection (b)(4) of that section—

"(1) that is reported to, or otherwise obtained by, the Administrator under this Act; and

"(2) for which the requirements of subsection (d) are met.

"(b) Information Generally Protected From Disclosure.—The following information specific to, and submitted by, a manufacturer, processor, or distributor that meets the requirements of subsections (a) and (d) shall be presumed to be protected from disclosure, subject to the condition that nothing in this Act prohibits the disclosure of any such information, or information that is the subject of subsection (g)(3), through discovery, subpoena, other court order, or any other judicial process otherwise allowed under applicable Federal or State law:

"(1) Specific information describing the processes used in manufacture or processing of a chemical substance, mixture, or article.

"(2) Marketing and sales information.

"(3) Information identifying a supplier or customer.

"(4) Details of the full composition of a mixture and the respective percentages of constituents.

"(5) Specific information regarding the use, function, or application of a chemical substance or mixture in a process, mixture, or product.

"(6) Specific production or import volumes of the manufacturer ~~and specific~~.

"(7) Specific aggregated volumes across manufacturers, if the Administrator determines that disclosure of the specific aggregated volumes would reveal confidential information.

~~"(7)~~**"(8)** Except as otherwise provided in this section, the specific identity of a chemical substance prior to the date on which the chemical substance is first offered for commercial distribution, including the chemical name, molecular formula, Chemical Abstracts Service number, and other information that would identify a specific chemical substance, **if** ~~if—~~

~~"(A)~~ the specific identity was claimed as confidential information at the time it was submitted in a notice under section 5~~; and~~

~~"(B) the claim—~~

~~"(i) is not subject to an exception under subsection (e); or~~

~~"(ii) has not subsequently been withdrawn or found by the Administrator not to warrant protection as confidential information under subsection (f)(2) or (g)~~.

Commented [A1]: As we have previously pointed out, it makes no sense to condition presumptive protection on whether the information actually meets the CBI standard in (a). In addition, this may increase the number of CBI claims EPA must review, since EPA may not be able treat information as falling under (b) and hence not subject to review without first determining it is CBI.

Commented [A2]: As we have previously pointed out, this proviso for *presumptive* CBI suggests that other CBI will be shielded from discovery, etc.

Commented [A3]: The point of this provision presumably is to protect chem id in advance of an NOC, but some pre-NOC distribution would likely be considered offered for commercial distribution under TSCA (e.g., distribution for R&D).

Conversely, some post-NOC manufacturing, processing, and distribution might not qualify as "offer[ing]" the chemical to another party, and so arguably might not fall under this heading.

"(c) Information Not Protected From ~~Disclosure.—Notwithstanding~~ **Disclosure.—**

"(1) IN GENERAL.—Notwithstanding subsections (a) and (b), the following information shall not be protected from disclosure:

~~"(1)~~**"(A)** INFORMATION FROM HEALTH AND SAFETY STUDIES.—

~~"(A)~~**"(i)** IN GENERAL.—Subject to ~~subparagraph (B), subsection (a) does not prohibit the disclosure of—~~ **clause (ii)—**

~~"(i)~~**"(I)** any health and safety study that is submitted under this Act with respect to—

~~"(I)~~**"(aa)** any chemical substance or mixture that, on the date on which the study is to be disclosed, has been offered for commercial distribution; or

~~"(II)~~**"(bb)** any chemical substance or mixture for which—

~~"(aa)~~**"(AA)** testing is required under section 4; or

~~"(bb)~~**"(BB)** a notification is required under section 5; or

~~"(ii)~~**"(II)** any information reported to, or otherwise obtained by, the Administrator from a health and safety study relating to a chemical substance or mixture described in ~~subclause (I) or (II) of clause (i).~~ **item (aa) or (bb) of subclause (I).**

~~"(B)~~**"(ii)** EFFECT OF ~~PARAGRAPH.—NOTHING~~ SUBPARAGRAPH.**—Nothing** in this ~~paragraph~~ **subparagraph** authorizes the release of any information that discloses—

~~"(i)~~**"(I)** a process used in the manufacturing or processing of a chemical substance or mixture; or

~~"(ii)~~**"(II)** in the case of a mixture, the portion of the mixture comprised by any chemical substance in the mixture.

~~* 4 "(2) Certain requests.—If a request is made to the Administrator under section 552(a) of title 5, United States Code, for information that is described in paragraph (1) that is not described in paragraph (1)(B), the Administrator may not deny the request on the basis of section 552(b)(4) of title 5, United States Code.~~

~~"(3)~~**"(B)** OTHER INFORMATION NOT PROTECTED FROM ~~DISCLOSURE.—THE FOLLOWING INFORMATION IS NOT PROTECTED FROM DISCLOSURE UNDER THIS SECTION:~~ DISCLOSURE.—

~~"(A)~~**"(i)** For information submitted after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the specific identity of a chemical substance as of the date on which the chemical substance is first offered for commercial distribution, if the person submitting the information does not meet the requirements of subsection (d).

~~"(B)~~**"(ii)** A safety assessment developed, or a safety determination made, under

Commented [A4]: As we have previously pointed out, this adds nothing and could create confusion, since the point it makes for specific chem id is true for all information – ie, it cannot be CBI if not properly claimed.

section 6.

~~"(C)~~**"(iii)** Any general information describing the manufacturing volumes, expressed as specific aggregated volumes or, if the Administrator determines that disclosure of specific aggregated volumes would reveal confidential information, expressed in ranges.

~~"(D)~~**"(iv)** A general description of a process used in the manufacture or processing and industrial, commercial, or consumer functions and uses of a chemical substance, mixture, or article containing a chemical substance or mixture, including information specific to an industry or industry sector that customarily would be shared with the general public or within an industry or industry sector.

~~"(4)~~**"(2)** MIXED CONFIDENTIAL AND NONCONFIDENTIAL INFORMATION .—Any information that is ~~otherwise~~ eligible for protection under this section and ~~contained in a submission of~~ **is submitted with** information described in this subsection shall be protected from disclosure, if the submitter complies with subsection (d), subject to the condition that information in the submission that is not eligible for protection against disclosure shall be disclosed.

~~"(5)~~**"(3)** BAN OR PHASE-OUT.—If the Administrator promulgates a rule pursuant to section 6(d) that establishes a ban or phase-out of the manufacture, processing, or distribution in commerce of a chemical substance, subject to paragraphs (2), (3), and (4) of subsection (g), any protection from disclosure provided under this section with respect to the specific identity of the chemical substance and other information relating to the chemical substance shall no longer apply.

** **4** ~~"(2)~~**"(4)** CERTAIN REQUESTS.—If a request is made to the Administrator under section 552(a) of title 5, United States Code, for information that is ~~described in paragraph (1) that is not described in paragraph (1)(B)~~ **subject to disclosure under this subsection**, the Administrator may not deny the request on the basis of section 552(b)(4) of title 5, United States Code.

"(d) Requirements for Confidentiality Claims.—

"(1) ASSERTION OF CLAIMS.—

"(A) IN GENERAL.—A person seeking to protect any information submitted under this Act from disclosure (including information described in subsection (b)) shall assert to the Administrator a claim for protection concurrent with submission of the information, in accordance with such rules regarding a claim for protection from disclosure as the Administrator has promulgated or may promulgate pursuant to this title.

"(B) INCLUSION.—An assertion of a claim under subparagraph (A) shall include a statement that the person has—

"(i) taken reasonable measures to protect the confidentiality of the information;

"(ii) determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law;

"(iii) a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of the person; and

"(iv) a reasonable basis to believe that the information is not readily discoverable through reverse engineering.

"(C) SPECIFIC CHEMICAL IDENTITY.—In the case of a claim under subparagraph (A) for protection against disclosure of a specific chemical identity, the claim shall include a structurally descriptive generic name for the chemical substance that the Administrator may disclose to the public, subject to the condition that the generic name shall—

"(i) ~~conform~~ **be consistent** with guidance ~~prescribed~~ **issued** by the Administrator under paragraph (3)(A); and

"(ii) describe the chemical structure of the substance as specifically as practicable while protecting those features of the chemical structure—

"(I) that are considered to be confidential; and

"(II) the disclosure of which would be likely to **cause substantial** harm **to** the competitive position of the person.

"(D) PUBLIC INFORMATION.—No person may assert a claim under this section for protection from disclosure of information that is already publicly available.

"(2) ADDITIONAL REQUIREMENTS FOR CONFIDENTIALITY CLAIMS.—Except for information described in ~~paragraphs (1) through (7) of~~ subsection (b), a person asserting a claim to protect information from disclosure under this Act shall substantiate the claim, in accordance with the rules promulgated and **consistent with the** guidance issued by the Administrator.

"(3) GUIDANCE.—The Administrator shall develop guidance regarding—

"(A) the determination of structurally descriptive generic names, in the case of claims for the protection against disclosure of specific chemical identity; and

"(B) the content and form of the statements of need and agreements required under paragraphs (4), (5), and (6) of subsection (e).

"(4) CERTIFICATION.—An authorized official of a person described in paragraph (1)(A) shall certify that the ~~information that has been submitted is~~ **statement required to assert a claim submitted pursuant to paragraph (1)(B) and any information required to substantiate a claim submitted pursuant to paragraph (2) are** true and correct.

"(e) Exceptions to Protection From Disclosure.—Information described in subsection (a)—

"(1) shall be disclosed if the information is to be disclosed to an officer or employee of the United States in connection with the official duties of the officer or employee—

"(A) under any law for the protection of health or the environment; or

"(B) for a specific law enforcement purpose;

"(2) shall be disclosed if the information is to be disclosed to a contractor of the United States and employees of that contractor—

"(A) if, in the opinion of the Administrator, the disclosure is necessary for the satisfactory performance by the contractor of a contract with the United States for the performance of work in connection with this Act; and

"(B) subject to such conditions as the Administrator may specify;

"(3) shall be disclosed if the Administrator determines that disclosure is necessary to protect health or the environment;

"(4) shall be disclosed if the information is to be disclosed to a State or political subdivision of a State, on written request, for the purpose of development, administration, or enforcement of a law, **if** ~~if~~—

~~"(A)~~ 1 or more applicable agreements with the Administrator that ~~conform~~ **are consistent** with the guidance issued under subsection (d)(3)(B) ensure that the recipient will take appropriate measures, and has adequate authority, to maintain the confidentiality of the information in accordance with procedures comparable to the procedures used by the Administrator to safeguard the information; ~~and~~

~~"(B) the Administrator notifies the person that submitted the information that the information has been disclosed to the State or political subdivision of a State;~~

"(5) shall be disclosed if a health or environmental professional employed by a Federal or State agency or a treating physician or nurse in a nonemergency situation provides a written statement of need and agrees to sign a written confidentiality agreement with the Administrator, subject to the conditions that—

"(A) the statement of need and confidentiality agreement ~~shall conform~~ **are consistent** with the guidance issued under subsection (d)(3)(B);

"(B) the written statement of need shall be a statement that the person has a reasonable basis to suspect that—

"(i) the information is necessary for, or will assist in—

"(I) the diagnosis or treatment of 1 or more individuals; or

"(II) responding to an environmental release or exposure; and

"(ii) 1 or more individuals being diagnosed or treated have been exposed to the chemical substance concerned, or an environmental release or exposure has occurred; and

"(C) the confidentiality agreement shall provide that the person will not use the information for any purpose other than the health or environmental needs asserted in the statement of need, except as otherwise may be authorized by the terms of the agreement or by the person submitting the information to the Administrator, except that nothing in this Act prohibits the disclosure of any such information through discovery, subpoena, other court order, or any other judicial process otherwise allowed under applicable Federal or State law;

"(6) shall be disclosed if in the event of an emergency, a treating physician, nurse, agent of a poison control center, public health or environmental official of a State or political subdivision of a State, or first responder (including any individual duly authorized by a

Federal agency, State, or political subdivision of a State who is trained in urgent medical care or other emergency procedures, including a police officer, firefighter, or emergency medical technician) requests the information, subject to the conditions that—

"(A) the treating physician, nurse, agent, public health or environmental official of a State or a political subdivision of a State, or first responder shall have a reasonable basis to suspect that—

"(i) a medical or public health or environmental emergency exists;

"(ii) the information is necessary for, or will assist in, emergency or first-aid diagnosis or treatment; or

"(iii) 1 or more individuals being diagnosed or treated have likely been exposed to the chemical substance concerned, or a serious environmental release of or exposure to the chemical substance concerned has occurred;

"(B) if requested by the person submitting the information to the Administrator, the treating physician, nurse, agent, public health or environmental official of a State or a political subdivision of a State, or first responder shall, as described in paragraph (5)—

"(i) provide a written statement of need; and

"(ii) agree to sign a confidentiality agreement; and

"(C) the written confidentiality agreement or statement of need shall be submitted as soon as practicable, but not necessarily before the information is disclosed;

"(7) may be disclosed if the Administrator determines that disclosure is relevant in a proceeding under this Act, subject to the condition that the disclosure shall be made in such a manner as to preserve confidentiality to the maximum extent practicable without impairing the proceeding;

"(8) shall be disclosed if the information is to be disclosed, on written request of any duly authorized congressional committee, to that committee; or

"(9) shall be disclosed if the information is required to be disclosed or otherwise made public under any other provision of Federal law.

"(f) Duration of Protection From Disclosure.—

"(1) IN GENERAL.—

"(A) INFORMATION ~~PROTECTED~~ **NOT SUBJECT TO TIME LIMIT FOR PROTECTION** FROM DISCLOSURE.—Subject to paragraph (2), the Administrator shall protect from disclosure information **described in subsection (b)** that meets the requirements of ~~subsection (d) for a period of 10 years, unless, prior to the expiration of the period—~~ **subsections (a) and (d), unless—**

~~"(i) an affected person~~ **"(i) the person that asserted the claim** notifies the Administrator that the person is withdrawing the ~~confidentiality~~ claim, in which case the Administrator shall promptly make the information available to the public; or

"(ii) the Administrator otherwise becomes aware that the ~~need for protection from disclosure can no longer be substantiated~~ **information does not qualify or**

no longer qualifies for protection against disclosure under subsection (a), in which case the Administrator shall take ~~the~~ **any** actions ~~described in~~ **required under** subsection (g)(2).

"(B) **INFORMATION SUBJECT TO TIME LIMIT FOR PROTECTION FROM DISCLOSURE.—Subject to paragraph (2), the Administrator shall protect from disclosure information, other than information described in subsection (b), that meets the requirements of subsections (a) and (d) for a period of 10 years, unless, prior to the expiration of the period—**

"(i) the person that asserted the claim notifies the Administrator that the person is withdrawing the claim, in which case the Administrator shall promptly make the information available to the public; or

"(ii) the Administrator otherwise becomes aware that the information does not qualify or no longer qualifies for protection against disclosure under subsection (a), in which case the Administrator shall take any actions required under subsection (g)(2).

"(C) EXTENSIONS.—

"(i) IN GENERAL.—Not later than the date that is 60 days before the expiration of the period described in subparagraph ~~(A)~~**(B)**, the Administrator shall provide to the person that asserted the claim a notice of the impending expiration of the period.

"(ii) STATEMENT.—

"(I) IN GENERAL.—Not later than the date that is 30 days before the expiration of the period described in subparagraph ~~(A)~~**(B)**, a person reasserting the relevant claim shall submit to the Administrator a ~~statement~~ **request for extension** substantiating, in accordance with subsection (d)(2), the need to extend the period.

"(II) ACTION BY ADMINISTRATOR.—Not later than the date ~~that is 30 days after the date of receipt of a statement under subclause (I), the Administrator shall—~~ **of expiration of the period described in subparagraph (B), the Administrator shall, in accordance with subsection (g)(1)(C)—**

"(aa) review the request **submitted under subclause (I)**;

"(bb) make a determination regarding whether the ~~information~~ **claim** for which the request ~~is made~~ **was submitted** continues to meet the relevant criteria established under this section; and

"(cc)(AA) grant an extension of ~~not more than~~ 10 years; or

"(BB) deny the ~~claim.~~ **request.**

"~~(C)~~**"(D)** NO LIMIT ON NUMBER OF EXTENSIONS.—There shall be no limit on the number of extensions granted under subparagraph ~~(B)~~**(C)**, if the Administrator determines that the relevant ~~statement~~ **request** under subparagraph ~~(B)(ii)(I)~~ **(C)(ii)(I)—**

"(i) establishes the need to extend the period; and

"(ii) meets the requirements established by the Administrator.

"(2) REVIEW AND RESUBSTANTIATION.—

"(A) DISCRETION OF ADMINISTRATOR.—The Administrator may review, at any time, a claim for protection **of information** against disclosure under subsection (a) ~~for information submitted to the Administrator regarding a chemical substance~~ and require any person that has claimed protection for that information, whether before, on, or after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, to withdraw or reassert and substantiate or resubstantiate the claim in accordance with this section—

"(i) after the chemical substance is identified as a high-priority substance under section 4A;

"(ii) for any chemical substance for which the Administrator has made a determination under section 6(c)(1)(C);

"(iii) for any inactive chemical substance identified under section 8(b)(5); or

"(iv) in limited circumstances, if the Administrator determines that disclosure of certain information currently protected from disclosure would assist the Administrator in conducting safety assessments and safety determinations under subsections (b) and (c) of section 6 or promulgating rules pursuant to section 6(d)~~, subject to the condition that the information shall not be disclosed unless the claimant withdraws the claim or the Administrator determines that the information does not meet the requirements of subsection (d)~~.

Commented [A5]: Reference should be to 8(b)(5)(B) specifically – change to active status.

"(B) REVIEW REQUIRED.—The Administrator shall review a claim for protection ~~from~~ **of information against** disclosure under subsection (a) ~~for information submitted to the Administrator regarding a chemical substance~~ and require any person that has claimed protection for that information, whether before, on, or after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, to withdraw or reassert and substantiate or resubstantiate the claim in accordance with this section—

"(i) as necessary to ~~comply~~ **determine whether the information qualifies for an exemption from disclosure in connection** with a request for information received by the Administrator under section 552 of title 5, United States Code;

"(ii) if ~~information available to the Administrator provides a basis that the requirements of section 552(b)(4) of title 5, United States Code, are no longer met;~~ **the Administrator has a reasonable basis to believe that the information does not qualify for protection against disclosure under subsection (a);** or

"(iii) for any substance for which the Administrator has made a determination under section 6(c)(1)(B).

"(C) ACTION BY RECIPIENT.—If the Administrator makes a request under subparagraph (A) or (B), the recipient of the request shall—

"(i) reassert and substantiate or resubstantiate the claim; or

"(ii) withdraw the claim.

"(D) PERIOD OF PROTECTION.—Protection from disclosure of information subject to a claim that is reviewed and approved by the Administrator under this paragraph shall be extended for a period of 10 years from the date of approval, subject to any subsequent request by the Administrator under this paragraph.

"(3) UNIQUE IDENTIFIER.—The Administrator shall—

"(A)(i) develop a system to assign a unique identifier to each specific chemical identity for which the Administrator approves a request for protection from disclosure, other than a specific chemical identity or structurally descriptive generic term; and

"(ii) apply that identifier consistently to all information relevant to the applicable chemical substance;

"(B) annually publish and update a list of chemical substances, referred to by unique identifier, for which claims to protect the specific chemical identity from disclosure have been approved, including the expiration date for each such claim;

"(C) ensure that any nonconfidential information received by the Administrator with respect to such a chemical substance during the period of protection from disclosure—

"(i) is made public; and

"(ii) identifies the chemical substance using the unique identifier; and

"(D) for each claim for protection of specific chemical identity that has been denied by the Administrator ~~on expiration of the period for appeal under subsection (g)(4), that has~~ **or** expired, or that has been withdrawn by the submitter, provide public access to the specific chemical identity clearly linked to all nonconfidential information received by the Administrator with respect to the chemical substance.

"(g) Duties of Administrator.—

"(1) DETERMINATION.—

"(A) IN GENERAL.—Except as provided in subsection (b), the Administrator shall, subject to subparagraph (C), not later than 90 days after the receipt of a claim under subsection (d), and not later than 30 days after the receipt of a request for extension of a claim under subsection (f), review and approve, modify, or deny the claim or request.

Commented [A6]: It is confusing to refer to EPA "modifying," the claims of a 3rd party. EPA can't change the fact that some 3rd party claims something, but the intent here seems to be to allow EPA to approve a subset of the full claim. It would be clearer to refer to say: "approve, approve in part, or deny"

"(B) **REASONS FOR DENIAL OR MODIFICATION.—If the Administrator denies or modifies a claim or request under subparagraph (A)** ~~Denial or modification.—~~

~~"(i) In general.—Except as provided in subsections (c) and (f),~~ the Administrator shall **provide to the person that submitted the claim or request** ~~deny a claim to protect a chemical identity from disclosure only if the person that has submitted the claim fails to meet the requirements of subsections (a) and (d).~~

~~"(ii) Reasons for denial or modification.—The Administrator shall provide to a person that has submitted a claim described in clause (i)~~ a written statement of the reasons for the denial or modification of the claim **or request**.

"(C) SUBSETS.—The Administrator shall—

"(i) except for claims described in subsection ~~(b)(7)~~**(b)(8)**, review all claims **or requests** under this section for the protection against disclosure of the specific identity of a chemical substance; and

"(ii) review a representative subset, comprising at least 25 percent, of all other claims **or requests** for protection against disclosure.

"(D) EFFECT OF FAILURE TO ACT.—The failure of the Administrator to make a decision regarding a claim **or request** for protection against disclosure or extension under this section shall not be the basis for denial or elimination of a claim **or request** for protection against disclosure.

"(2) NOTIFICATION.—

"(A) IN GENERAL.—Except as provided in subparagraph (B) and subsections (c), (e), and (f), if the Administrator denies or modifies a claim **or request** under paragraph (1), **intends to release information pursuant to subsection (e),** or promulgates a rule under section 6(d) establishing a ban or phase-out of a chemical substance, the Administrator shall notify, in writing and by certified mail, the person that submitted the claim of the intent of the Administrator to release the information.

Commented [A7]: This specifies three bases on which information claimed CBI might be released, but misses an important basis: where EPA determines protection is not warranted at some point during the protection period.

Commented [A8]: Certified mail is a cumbersome form of notification.

"(B) RELEASE OF INFORMATION.—**Except** ~~information.—~~

~~"(i) In general.—Except~~ as provided in ~~clause (ii)~~ **subparagraph (C)**, the Administrator shall not release information under this subsection until the date that is 30 days after the date on which the person that submitted the request receives notification under subparagraph (A).

~~"(ii)~~**"(C)** EXCEPTIONS.—

~~"(I)~~**"(i)** IN GENERAL.—For information under paragraph (3) or (8) of subsection (e), the Administrator shall not release that information until the date that is 15 days after the date on which the person that submitted the claim **or request** receives a notification, unless the Administrator determines that release of the information is necessary to protect against an imminent and substantial harm to health or the environment, in which case no prior notification shall be necessary.

"(ii) NOTIFICATION AS SOON AS PRACTICABLE.—For information under paragraphs (4) and (6) of subsection (e), the Administrator shall notify the person that submitted the information that the information has been disclosed as soon as practicable after disclosure of the information.

"(iii) NO NOTIFICATION REQUIRED.—Notification shall not be required—

"(I) for the disclosure of ~~"(II) No notification.—For~~ information under paragraph (1), (2), ~~(6),~~(7), or (9) of subsection (e)~~, no prior notification shall be necessary.~~**; or**

"(II) for the disclosure of information for which—

"(aa) a notice under subsection (f)(1)(C)(i) was received; and

"(bb) no request was received by the Administrator on or before the date of expiration of the period for which protection from

disclosure applies.

"(3) REBUTTABLE PRESUMPTION.—

"(A) IN GENERAL.—With respect to notifications provided by the Administrator ~~pursuant to subsection (c)(5)~~ **under paragraph (2) with respect to information pertaining to a chemical substance subject to a rule as described in subsection (c)(3)**, there shall be a rebuttable presumption that the public interest in disclosing confidential information related to a chemical substance subject to a rule promulgated under section 6(d) that establishes a ban or phase-out of the manufacture, processing, or distribution in commerce of the substance outweighs the proprietary interest in maintaining the protection from disclosure of that information.

"(B) REQUEST FOR NONDISCLOSURE.—A person that receives a notification under paragraph (2) with respect to the information described in subparagraph (A) may submit to the Administrator, before the date on which the information is to be released **pursuant to paragraph (2)(B)**, a request with supporting documentation describing why the person believes some or all of that information should not be disclosed.

"(C) DETERMINATION BY ADMINISTRATOR.—

"(i) IN GENERAL.—Not later than 30 days after the Administrator receives a request under subparagraph (B), the Administrator shall determine~~, at the discretion of the Administrator,~~ whether the documentation provided by the person making the request rebuts or does not rebut the presumption described in subparagraph (A), for all or a portion of the information that the person has requested not be disclosed.

"(ii) OBJECTIVE.—The Administrator shall make the determination with the objective of ensuring that information relevant to protection of health and the environment is disclosed to the maximum extent practicable.

"(D) TIMING.—Not later than 30 days after making the determination described in subparagraph (C), the Administrator shall make public the information the Administrator has determined is not to be protected from disclosure.

"(E) NO TIMELY REQUEST RECEIVED.—If the Administrator does not receive, before the date on which the information described in subparagraph (A) is to be released **pursuant to paragraph (2)(B)**, a request pursuant to subparagraph (B), the Administrator shall promptly make public all of the information.

"(4) APPEALS.—

"(A) IN GENERAL.—If a person receives a notification under paragraph (2) and believes disclosure of the information is prohibited under subsection (a), before the date on which the information is to be released **pursuant to paragraph (2)(B)**, the person may bring an action to restrain disclosure of the information in—

"(i) the United States district court of the district in which the complainant resides or has the principal place of business; or

"(ii) the United States District Court for the District of Columbia.

"(B) NO DISCLOSURE.—The Administrator shall not disclose any information that is

the subject of an appeal under this section before the date on which the applicable court rules on an action under subparagraph (A).

"(5) ~~ADMINISTRATION.—IN CARRYING OUT THIS SUBSECTION, THE ADMINISTRATOR SHALL USE THE PROCEDURES DESCRIBED IN PART 2 OF TITLE 40, CODE OF FEDERAL REGULATIONS (OR SUCCESSOR REGULATIONS).~~ **REQUEST AND NOTIFICATION SYSTEM.—The Administrator, in consultation with the Director of the Centers for Disease Control and Prevention, shall develop a request and notification system that allows for expedient and swift access to information disclosed pursuant to paragraphs (5) and (6) of subsection (e) in a format and language that is readily accessible and understandable.**

Commented [A9]: ***This provision is confusing. The "information" in question would already have been submitted to EPA, so how would EPA be able to determine the format and language of the information? Also, subsection (g) already provides the timeframes for release of the info, so what more would EPA do to allow for expedient and swift access?

"(h) Criminal Penalty for Wrongful Disclosure.—

"(1) OFFICERS AND EMPLOYEES OF UNITED STATES.—

"(A) IN GENERAL.—Subject to paragraph (2), a current or former officer or employee of the United States described in subparagraph (B) shall be guilty of a misdemeanor and fined under title 18, United States Code, or imprisoned for not more than 1 year, or both.

"(B) DESCRIPTION.—A current or former officer or employee of the United States referred to in subparagraph (A) is a current or former officer or employee of the United States who—

"(i) by virtue of that employment or official position has obtained possession of, or has access to, material the disclosure of which is prohibited by subsection (a); and

"(ii) knowing that disclosure of that material is prohibited by subsection (a), willfully discloses the material in any manner to any person not entitled to receive that material.

"(2) OTHER LAWS.—Section 1905 of title 18, United States Code, shall not apply with respect to the publishing, divulging, disclosure, making known of, or making available, information reported or otherwise obtained under this Act.

"(3) CONTRACTORS.—For purposes of this subsection, any contractor of the United States that is provided information in accordance with subsection (e)(2), including any employee of that contractor, shall be considered to be an employee of the United States.

"(i) Applicability.—

"(1) IN GENERAL.—Except as otherwise provided in this section, section 8, or any other applicable Federal law, the Administrator shall have no authority—

"(A) to require the substantiation or resubstantiation of a claim for the protection from disclosure of information ~~submitted to~~ **reported to or otherwise obtained by** the Administrator under this Act before the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act; or

"(B) to impose substantiation or resubstantiation requirements under this Act that are more extensive than those required under this section.

"(2) ~~PRIOR ACTIONS.—NOTHING~~ **ACTIONS PRIOR TO PROMULGATION OF RULES.—** **Nothing** in this Act prevents the Administrator from reviewing, requiring substantiation or resubstantiation for, or approving, modifying or denying any claim for the protection from disclosure of information before the effective date of such rules applicable to those claims as the Administrator may promulgate after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.".

Commented [A10]: It is confusing to refer to EPA "modifying," the claims of a 3rd party. EPA can't change the fact that some 3rd party claims something, but the intent here seems to be to allow EPA to approve a subset of the full claim. It would be clearer to refer to say: "approving, approving in part, or denying"

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/11/2016 5:55:19 PM
To: 'Black, Jonathan (Tom Udall)' [Jonathan_Black@tomudall.senate.gov]
Subject: RE: Sen. Udall TSCA TA request on Industry nominated chemicals

Jonathan,
That's helpful – we're on it. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Monday, April 11, 2016 1:55 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Re: Sen. Udall TSCA TA request on Industry nominated chemicals

No, it's my bad.

The new offer.

I think they should both be the same on this provision?

Sent from my BlackBerry 10 smartphone on the Verizon Wireless 4G LTE network.

From: Kaiser, Sven-Erik
Sent: Monday, April 11, 2016 1:52 PM
To: Black, Jonathan (Tom Udall)
Subject: RE: Sen. Udall TSCA TA request on Industry nominated chemicals

Jonathan – Apologies about the mix up. Can you confirm which version to work from - senate offer (3/3) or new senate offer that came in over the weekend. Thanks,
Sven

Sven-Erik Kaiser
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Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Monday, April 11, 2016 1:44 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Re: Sen. Udall TSCA TA request on Industry nominated chemicals

Thanks Sven, I should have asked for you to draft to the Senate offer.

Possible to see that? Sorry.

Sent from my BlackBerry 10 smartphone on the Verizon Wireless 4G LTE network.

From: Kaiser, Sven-Erik
Sent: Monday, April 11, 2016 1:33 PM
To: Black, Jonathan (Tom Udall)
Subject: Sen. Udall TSCA TA request on Industry nominated chemicals

Jonathan,
This TA responds to the request on industry nominated chemicals.

QUESTION: EPA has indicated that the House bill allows industry nominated chemicals to overwhelm EPA's priorities.

Is there a way to draft the house bill/proposal to allow for industry nominated chemicals to move through "without a cap" (as per the senate bill), but also without compromising EPA's priorities?

Response:
The language in question is for the House offer. It would also work with minor adjustment for the House bill as passed. There is no min/max provision in the House bill as passed, so that part has to be deleted if you are modifying the House bill as passed.

House offer

6(b)(7) MINIMUM NUMBER.--

(A) IN GENERAL.-- Subject to the availability of appropriations, the Administrator shall initiate 10 or more risk evaluations under paragraph (3)(A)(i) or (3)(B) in each fiscal year beginning in the fiscal year of the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

(B) LIMITATION.-- Notwithstanding any other provision of this section, if the Administrator does not initiate 10 or more risk evaluations under (A) in any complete fiscal year following the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, then in the following fiscal year the Administrator shall not accept any requests under paragraph (3)(A)(ii) and is not subject to paragraph (3)(C)(i)(I), unless in that fiscal year the Administrator has first initiated 10 risk evaluations under (A).

House bill as passed

6(b)(7) MINIMUM NUMBER.--

(A) IN GENERAL.-- Subject to the availability of appropriations, the Administrator shall initiate 10 or more risk evaluations under paragraph (3)(A)(i) or (3)(B) in each fiscal year beginning in the fiscal year of the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

(B) LIMITATION.-- Notwithstanding any other provision of this section, if the Administrator does not initiate 10 or more risk evaluations under (A) in any complete fiscal year following the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, then in the following fiscal year the Administrator shall not accept any

requests under paragraph (3)(A)(ii) unless in that fiscal year the Administrator has first initiated 10 risk evaluations under (A).

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: "Black, Jonathan (Tom Udall)" <Jonathan_Black@tomudall.senate.gov>
Date: April 10, 2016 at 6:07:41 PM EDT
To: "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov>
Subject: Industry nominated chemicals

Hi Sven,

EPA has indicated that the House bill allows industry nominated chemicals to overwhelm EPA's priorities.

Is there a way to draft the house bill/proposal to allow for industry nominated chemicals to move through "without a cap" (as per the senate bill), but also without compromising EPA's priorities?

Sent from my BlackBerry 10 smartphone on the Verizon Wireless 4G LTE network.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/17/2016 1:55:58 PM
To: 'Black, Jonathan (Tom Udall)' [Jonathan_Black@tomudall.senate.gov]
Subject: Sen. Udall TSCA TA Request on New Chemicals and Senate Proposal

Jonathan,
Got it - checking. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Thursday, March 17, 2016 9:55 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: New Chemicals and Senate Proposal

Hi Sven, is it possible to get some kind of compare and contrast on the Senate Proposal for Section 5 with the way the current new chemicals program is being run?

Some way to show what is similar/different from current Administration practice?

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/19/2016 11:26:54 PM
To: Michal_Freedhoff@markey.senate.gov
Subject: TSCA TA on HLC section 26 (4-18)
Attachments: image001.png; ATT00001.htm; image002.png; ATT00002.htm; image003.png; ATT00003.htm; image004.jpg; ATT00004.htm; SENATE_compared to_HOUSE Section 26 TA.docx; ATT00005.htm

Michal,
The TA below and attached responds to the request on HLC section 26 (4-18) including the question about partial risk evaluations.

We think that referencing the IQA in the manner suggested would make compliance with the IQA judicially reviewable in this context, setting a precedent in a statute with language allowing judicial review of IQA compliance. Up till now, IQA compliance has not been judicially reviewable.

Referencing the section 26 science provisions as you suggest would now subject those partial REs to standards that were not applicable at the time the risk assessments were completed. In essence, those requirements would become retroactively applicable to the completed risk assessments.

In that regard, we note that the new section 26 in the HLC version that we are still reviewing, as well as the last SLC version we have, still had the language at the end of the partial RE section (page 13, lines 18-19) that we had recommended striking in earlier TA. That language, "as in effect before such date of enactment", would subject the rulemakings on these substances to the current section 6 requirements (e.g., least burdensome), which we did not think was the intent of this provision.

Additional Items of major policy note:

Page 1, line 17 - Retention of older language that might necessitate keeping separate accounts for what money can be spent on which chemicals … must be the same chemical for which fees collected.

Page 3, lines 2-6 - Retention of older "provisions" language that creates an argument we can't spend fees on risk management or CBI work

Page 18, line 7 - narrowed the scope of one of the provisions that is supposed to prevent litigation over policies and procedures from being used to undermine previously completed risk evaluations, etc.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any questions. Thanks,

Sven

Sven-Erik Kaiser

U.S. EPA

Office of Congressional and Intergovernmental Relations

1200 Pennsylvania Ave., NW (1305A)

Washington, DC 20460

202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, April 19, 2016 5:01 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Cc: Deveny, Adrian (Merkley) <Adrian_Deveny@merkley.senate.gov>; Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>
Subject: partial REs

For after you finish with 5, and only if it is not going to delay you sending 26 (it is a 26 issue).

I am wondering if this is why House keeps baking least burdensome back into the partial RE language in 26. I'm not at all interested in the suggested CSAC approach as it won't exist in the right timeframe. I'd be interested in your thoughts on the IQA idea, but am thinking it probably makes sense to cite to the science language in 26 in the partial RE section and be done. I'd be interested in your thoughts

michal

Michal Ilana Freedhoff, Ph.D.

Director of Oversight & Investigations

Office of Senator Edward J. Markey

255 Dirksen Senate Office Building

Washington, DC 20510

202-224-2742

Connect with Senator Markey

[DISCUSSION DRAFT]

SEC. ll. ADMINISTRATION OF THE ACT.

Section 26 of the Toxic Substances Control Act (15 U.S.C. 2625) is amended—

(1) in subsection (b)(1)—

(A) by striking "of a reasonable fee";

(B) by striking "section 4 or 5 to defray the cost of administering this Act" and inserting "section 4 or a notice or other ϕdata / *information? this needs to be decided, and if the change is being made throughout, there are other places in TSCA that may need amending*¿ to be reviewed by the Administrator under section 5, or who manufactures or processes a chemical substance that is the subject of a risk evaluation under section 6(b), of a fee that is sufficient and not more than reasonably necessary to defray the cost related to such chemical substance of administering sections 4, 5, and 6, and collecting, processing, reviewing, and providing access to and protecting from disclosure as appropriate under section 14 information on chemical substances under this title, including

Commented [A1]: SLC version uses "information."

Since this is specifically a reference to information under section 4, this should be information to conform to the usage in section 4.

Commented [A2]: This phrase is not in SLC version.

Inclusion of this phrase will require EPA to maintain chemical-specific accounts to ensure that fees collected in relation to Chemical X are not spent on work in relation to Chemical Y, which will substantially complicate the budgeting process.

contractor costs incurred by the Administrator";

(C) by striking "Such rules shall not provide for any fee in excess of $2,500 or, in the case of a small business concern, any fee in excess of $100."; and

(D) by striking "submit the data and the cost to the Administrator of reviewing such data" and inserting "pay such fee and the cost to the Administrator of carrying out the activities described in this paragraph";

(2) by adding at the end of subsection (b) the following:

"(3) FUND.—

"(A) ESTABLISHMENT.—There is established in the Treasury of the United States a fund, to be known as the TSCA Service Fee Fund (in this paragraph referred to as the 'Fund'), consisting of such amounts as are deposited in the Fund under this paragraph.

"(B) COLLECTION AND DEPOSIT OF FEES.—The Administrator shall collect the fees described in this subsection and deposit those fees in the Fund.

"(C) CREDITING AND AVAILABILITY OF FEES.—On request by the Administrator, the Sec-

Commented [A3]: "the" in SLC version

Commented [A4]: SLC says "subparagraph (A)" because they have imposed a new paragraph structure on this passage from current TSCA.

Commented [A5]: SLC amends paragraph (2) to refer to paragraph (4) rather than paragraph (1) respecting small businesses. HLC makes no change and retains current TSCA reference to (1). A change is necessary because reference to small business concerns in (1) has been deleted.

Commented [A6]: "referred to in this paragraph as the 'Fund' – SLC version

Commented [A7]: "the" - SLC

retary of the Treasury shall transfer from the Fund to the Administrator amounts appropriated to pay or recover the costs incurred by the Environmental Protection Agency in carrying out the provisions of this title for which the fees are collected under paragraph (1).

"(D) USE OF FUNDS BY ADMINISTRATOR.—Fees authorized under this section shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts, and shall be available without fiscal year limitation for use in defraying the costs of the activities described in subsection (b)(1).

"(E) ACCOUNTING AND AUDITING.—

"(i) ACCOUNTING.—The Administrator shall biennially prepare and submit to the Committee on Environment and Public Works of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that includes an accounting of the fees paid to the Administrator under this paragraph and amounts disbursed from the Fund for the period covered by the report, as reflected by financial statements provided in accordance with

Commented [A8]: "for use in defraying the costs of the activities described in" – SLC

Retention of this House language may prevent EPA from spending fees on section 6 risk management work or on CBI work (since these activities are not provisions specifically associated with fees triggers)

Commented [A9]: "including contractor costs" – SLC

Commented [A10]: "paragraph (b)(1)" - SLC

sections 3515 and 3521 of title 31, United States Code.

"(ii) AUDITING.—

"(I) IN GENERAL.—For the purpose of section 3515(c) of title 31, United States Code, the Fund shall be considered a component of a covered executive agency.

"(II) COMPONENTS OF AUDIT.—The annual audit required in accordance with sections 3515 and 3521 of title 31, United States Code, of the financial statements of activities carried out using amounts from the Fund shall include an analysis of—

"(aa) the fees collected and amounts disbursed under this subsection;

"(bb) the reasonableness of the fees in place as of the date of the audit to meet current and projected costs of administering the provisions of this title for which the fees may be used; and

"(cc) the number of requests for a risk evaluation made by manufacturers under ø section 6(b)(4)(C)(ii) ¿.

"(III) FEDERAL RESPONSIBILITY.—The Inspector General of the Environmental Protection Agency shall conduct the annual audit described in subclause (II) and submit to the Administrator a report that describes the findings and any recommendations of the Inspector General resulting from the audit.

"(4) AMOUNT AND ADJUSTMENT OF FEES; REFUNDS.—In setting fees under this section, the Administrator shall—

"(A) prescribe lower fees for small business concerns, after consultation with the Administrator of the Small Business Administration;

"(B) set the fees established under paragraph (1) at levels such that the fees will, in aggregate, provide a sustainable source of funds to annually defray—

"(i) the lower of—

"(I) 25 percent of the costs to the Administrator of carrying out sections 4, 5, and 6, and of collecting, processing, reviewing, and providing access to and protecting from disclosure as appropriate under section 14 information on chemical

Commented [A11]: "of" – not in SLC version

substances under this title, other than the costs to conduct and complete risk evaluations under ø section 6(b)(3)(A)(ii) ¿; or

"(II) $25,000,000 (subject to adjustment pursuant to subparagraph (F)); and

"(ii) the full costs and the 50-percent portion of the costs of risk evaluations specified in subparagraph (D)(ii);

"(C) reflect an appropriate balance in the assessment of fees between manufacturers and processors, and allow the payment of fees by consortia of manufacturers or processors;

"(D) notwithstanding subparagraph (B)—

"(i) for chemical substances for which the Administrator has granted a request from a manufacturer pursuant to ø section 6(b)(3)(A)(ii) ¿, establish the fee at a level sufficient to defray the full costs to the Administrator of conducting the risk evaluation under section 6;

"(ii) for chemical substances for which the Administrator has granted a request from a manufacturer pursuant to ø section 6(b)(3)(A)(ii) ¿, and which are included in the 2014 update of the TSCA Work Plan for

Commented [A12]: "for chemical substances identified pursuant to [section 6(b)(4)(C)(ii)];" - SLC

Commented [A13]: SLC just says "(D)" This should reference "(D)", in line with SLC. (D)(ii) covers only the 50% share, whereas this provision refers to both full share and 50% share.

Commented [A14]: SLC version begins with "except as provided in clause (ii)..."

The SLC text is important because otherwise these paragraphs tell you to do inconsistent things with respect to a chemical that is on the Work Plan *and* the subject of a request.

Commented [A15]: Different section reference here.

Commented [A16]: "section 6(b)" - SLC

Commented [A17]: Different section reference here.

Chemical Assessments, establish the fee at a level sufficient to defray 50 percent of the annual costs to the Administrator of conducting the risk evaluation under section 6; and

"(iii) fees collected pursuant to clauses (i) and (ii) shall be applied by the Administrator only to defray the costs described in clauses (i) and (ii);

"(E) prior to the establishment or amendment of any fees under paragraph (1), consult and meet with parties potentially subject to the fees or their representatives, subject to the condition that no obligation under the Federal Advisory Committee Act (5 U.S.C. App.) is applicable with respect to such meetings;

"(F) beginning with the fiscal year that is 3 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, and every 3 years thereafter, after consultation with parties potentially subject to the fees and their representatives pursuant to subparagraph (E), increase or decrease the fees established under paragraph (1) as necessary to adjust for inflation and to ensure that funds deposited in the Fund are sufficient to defray—

Commented [A18]: "Annual" is not in SLC version

Inconsistent use of annual cost vs. cost could create confusion --- e.g., "annual" not used in (i).

Commented [A19]: "6(b)" in SLC

Commented [A20]: "apply fees collected pursuant to clauses (i) and (ii) only to defray the costs described in those clauses." – SLC version

SLC version is the grammatically correct version. Passive voice construction of (iii) is not parallel with (i) and (ii).

Commented [A21]: "representatives of those parties" – SLC version

Commented [A22]: "or Subchapter II of Chapter 5 of title 5, United States code" – additional language in SLC version

SLC version would clarify that this rulemaking is not a negotiated rulemaking process.

Commented [A23]: "representatives of those parties" – SLC version

"(i) approximately but not more than 25 percent of the annual costs to the Administrator of carrying out sections 4, 5, and 6, and of collecting, processing, reviewing, and providing access to and protecting from disclosure as appropriate under section 14 information on chemical substances under this title, other than the costs to conduct and complete risk evaluations under section 6 for chemical substances under øsection 6(b)(3)(A)(ii)¿; and

Commented [A24]: "of" not in SLC version

Commented [A25]: Different reference in SLC version.

"(ii) the full annual costs and the 50-percent portion of the annual costs of risk evaluations specified in subparagraph (D); and

"(G) if a notice submitted under section 5 is not reviewed or such a notice is withdrawn, refund the fee or a portion of the fee if no substantial work was performed on the notice.

"(5) MINIMUM AMOUNT OF APPROPRIATIONS.—Fees may not be assessed for a fiscal year under this section unless the amount of appropriations for the Chemical Risk Review and Reduction program project of the Environmental Protection Agency for the fiscal year (excluding the amount of any fees appropriated for the fiscal year) are equal to or greater than the amount of appropriations for that program project for fiscal year 2014.

"(6) TERMINATION.—The authority provided by this subsection shall terminate at the conclusion of the fiscal year that is 10 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, unless otherwise reauthorized or modified by Congress."; and

(3) by adding at the end the following:

"(h) *HOUSE OFFER*: SCIENTIFIC STANDARDS.—In carrying out sections 4, 5, and 6, to the extent that the Administrator makes a decision based on science, the Administrator shall consider, as applicable—

"(1) the extent to which the scientific and technical procedures, measures, methods, or models employed to generate the information are reasonable for and consistent with the use of the information;

"(2) the extent to which the information is relevant for the Administrator's use in making a decision about a chemical substance or mixture;

"(3) the degree of clarity and completeness with which the data, assumptions, methods, quality assurance, and analyses employed to generate the information are documented;

"(4) the extent to which the variability and uncertainty in the information, or in the procedures,

Commented [A26]: Language NOT in SLC version.

Commented [A27]: SLC version says "shall use scientific information, technical procedures, measures, methods, protocols, methodologies, or models employed in a manner consistent with the best available science, and consider…."

Commented [A28]: SLC version – "scientific information, technical procedures…"

Commented [A29]: "protocols, methodologies, or…"

Commented [A30]: "intended" – SLC version

measures, methods, or models, are evaluated and characterized; and

"(5) the extent of independent verification or peer review of the information or of the procedures, measures, methods, or models.

"(h) *ALTERNATE*: SCIENTIFIC STANDARDS.—In carrying out sections 4, 5, and 6, to the extent that the Administrator makes a decision based on science, the Administrator shall use scientific information, technical procedures, measures, methods, protocols, methodologies, or models, employed in a manner consistent with the best available science, and shall consider as applicable—

"(1) the extent to which the scientific information, technical procedures, measures, methods, protocols, methodologies, or models employed to generate the information are reasonable for and consistent with the intended use of the information;

"(2) the extent to which the information is relevant for the Administrator's use in making a decision about a chemical substance or mixture;

"(3) the degree of clarity and completeness with which the data, assumptions, methods, quality assurance, and analyses employed to generate the information are documented;

Commented [A31]: "protocols, methodologies, or...." – SLC version

Commented [A32]: "protocols, methodologies, or...." – SLC version

Commented [A33]: This appears to be the SLC subsection (h)

"(4) the extent to which the variability and uncertainty in the information, or in the procedures, measures, methods, protocols, methodologies, or models, are evaluated and characterized; and

"(5) the extent of independent verification or peer review of the information or of the procedures, measures, methods, protocols, methodologies, or models.

"(i) WEIGHT OF SCIENTIFIC EVIDENCE.—The Administrator shall make decisions under sections 4, 5, and 6 based on the weight of the scientific evidence.

"(j) AVAILABILITY OF INFORMATION.—Subject to section 14, the Administrator shall make available to the public—

"(1) all notices, determinations, findings, rules, consent agreements, and orders of the Administrator under this title;

"(2) any information required to be provided to the Administrator under section 4;

"(3) a nontechnical summary of each risk evaluation conducted under section 6; and

"(4) a list of the studies considered by the Administrator in carrying out each such risk evaluation, along with and the results of those studies.

Commented [A34]: Not included in SLC version

"(k) REASONABLY AVAILABLE INFORMATION.—In carrying out sections 4, 5, and 6, the Administrator shall take into consideration information relating to a chemical substance or mixture, including hazard and exposure information, under the conditions of use, that is reasonably available to the Administrator.

"(l) POLICIES, PROCEDURES, AND GUIDANCE.—

"(1) DEVELOPMENT.—Not later than 2 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall develop any policies, procedures, and guidance the Administrator determines are necessary to carry out the amendments to this Act made by the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

"(2) REVIEW.—Not later than 5 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, and not less frequently than once every 5 years thereafter, the Administrator shall—

"(A) review the adequacy of the policies, procedures, and guidance developed under paragraph (1), including with respect to animal, nonanimal, and epidemiological test methods

Commented [A35]: SLC version includes extra language here as follows: "including policies, procedures, and guidance related to the use of scientific information described in subsection (h), and for the purpose of making the basis of decisions under sections 4, 5, and 6 clear to the public."

and procedures for assessing and determining risk under this title; and

"(B) revise such policies, procedures, and guidance as the Administrator determines necessary to reflect new scientific developments or understandings.

"(3) CHEMICAL SUBSTANCES WITH COMPLETED RISK ASSESSMENTS.—With respect to a chemical substance listed in the 2014 update to the TSCA Work Plan for Chemical Assessments for which the Administrator has published a completed risk assessment prior to the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator may publish proposed and final rules under section 6(a) that are consistent with the scope of the completed risk assessment for the chemical substance and consistent with other applicable requirements of section 6 as in effect before such date of enactment.

"(4) GUIDANCE.—Not later than 1 year after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall develop guidance to assist interested persons in developing and submitting draft risk evaluations which shall be considered by the Ad-

Commented [A36]: SLC version includes two additional paragraphs here: (3) Testing of Chemical Substances and Mixtures and (4) Integration of Prior Policies and Procedures

Commented [A37]: See paragraph (5) in SLC version

Commented [A38]: SLC version says "final"

House language has the advantage of not suggesting that a negative risk assessment is a final agency action prior to the finalization of the 6(a) rule.

Commented [A39]: Paragraph (7)(A) and (B) in SLC version, but identical.

ministrator. The guidance shall, at a minimum, address the quality of the information submitted and the process to be followed in developing draft risk evaluations for consideration by the Administrator.

"(m) REPORT TO CONGRESS.—

"(1) INITIAL REPORT.—Not later than 6 months after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall submit to the Committees on Energy and Commerce and Appropriations of the House of Representatives and the Committees on Environment and Public Works and Appropriations of the Senate a report containing an estimation of—

"(A) the capacity of the Environmental Protection Agency to conduct and publish risk evaluations under subparagraphs (A)(i) and (B) of section 6(b)(3), and the resources necessary to initiate the minimum number of risk evaluations required under øsection 6(b)(7)¿;

"(B) the capacity of the Environmental Protection Agency to conduct and publish risk evaluations under øsection 6(b)(3)(A)(ii)¿, the likely demand for such risk evaluations, and the

Commented [A40]: SLC version also includes a paragraph (6) on "Notice of Existing Information", which requires EPA to "take notice" of other information and Incorporate into risk evaluations.

Commented [A41]: Different cross references in SLC

Commented [A42]: Different cross reference in SLC

Commented [A43]: Different cross reference in SLC

Commented [A44]: "those" in SLC